

EXHIBIT 600

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY
LITIGATION

THIS DOCUMENT RELATES ONLY TO:

Kathy McCornack, an individual;)	MDL No. 2:09-CV-0671
Daniel E. McCornack, Jr., an)	
individual; and Ralph J.)	
McCornack, a minor by and)	
through his guardian ad litem,)	
)	
Plaintiffs,)	
)	
v.)	
)	
Actavis Totowa, LLC, et al.,)	
)	
Defendants.)	
_____)	

DEPOSITION OF LAWRENCE VON DOLLEN, M.D.

Monday, October 5, 2009

San Luis Obispo, California

2:03 p.m. - 4:26 p.m.

REPORTED BY CINDY D. GRIFFITH
CSR #7281

1 THE DEPOSITION OF LAWRENCE VON DOLLEN,
2 was taken at the offices of McDaniel Shorthand
3 Reporters, 1302 Osos Street, San Luis Obispo,
4 California, before Cindy D. Griffith, a Certified
5 Shorthand Reporter in and for the State of California,
6 on Monday, October 5, 2009, commencing at the hour of
7 2:03 p.m.

8
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1 I N D E X

2

3 WITNESS EXAMINATION BY PAGE

4 Lawrence Von Dollen, M.D. Mr. Moriarty 4

5 Ms. Donahue 88

6 Mr. Ernst 93

7

8 E X H I B I T S

9 FOR THE DEFENDANTS: PAGE

10 1 Curriculum Vitae 40

11 2 NMS Lab Report dated June 24th, 2008 49

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1 LAWRENCE VON DOLLEN, M.D.,
2 having been first duly sworn, was
3 examined and testified as follows:
4

5 EXAMINATION
6

7 BY MR. MORIARTY:

8 Q Tell us your full name, please.

9 A Lawrence Eugene Von Dollen.

10 Q Have you ever had your deposition taken before?

11 A Yes.

12 Q How many times?

13 A Twice.

14 Q At least the process is going to be the same.

15 I'm going to ask you relatively plain English questions.

16 I need your answers back to me. It can be scientific,

17 but certainly plain English. Okay?

18 Court reporters don't understand nods of the

19 head, shakes or hand gestures. Okay?

20 A Okay.

21 Q If you don't understand my question for
22 whatever reason, you let me know and I'll make it clear
23 to you. Okay?

24 A All right.

25 Q What were the circumstances under which you

1 have been -- had your deposition taken before?

2 A It's been so long ago, I'm difficult -- it's
3 hard for me to remember.

4 Once as a resident when a patient had an
5 allergic, questionable drug allergic reaction. This
6 would probably be 30 -- 20 some years ago.

7 I don't remember at the moment just what the
8 second one was about.

9 Q Were both of them medical negligence cases?

10 A I don't recall. The one with the allergy would
11 have been a question whether the patient had two disease
12 processes that were interrelated. And at that time it
13 was a questioning of allergy versus drug reaction. And
14 it's been so long ago, I can't remember the details.

15 Q Okay. All right. We appreciate you coming
16 down here today to do this down in San Luis Obispo.

17 What -- did you look at your office chart, the
18 computer version of your office chart for Mr. McCornack
19 before you came to testify today?

20 A Yes.

21 Q Other than that, did you review any documents
22 either hard paper or online?

23 A I received a copy of Dr. Lemm's office notes
24 several weeks ago.

25 Q Okay.

1 A And in previous conversations with Mr. Ernst
2 there had been the question of digoxin levels under
3 different circumstances. And he had shown me an
4 article, at my request, in one of our recent
5 conversations.

6 Q Who sent you Dr. Lemm's notes?

7 A Mr. Ernst.

8 Q And do you remember the name of the article?

9 A I'm sorry, I don't.

10 Q Do you remember the authors?

11 A No.

12 Q Do you remember the journals?

13 A No.

14 Q Do you remember the general topic?

15 A Um, would be digoxin levels in patients who had
16 died as composed with -- as compared with those that
17 when the specimen was drawn when they were living.

18 Q Have you heard of postmortem redistribution?

19 A Yes.

20 Q Is that what that article was about, the
21 postmortem redistribution of digoxin?

22 A That would have been -- I just glanced at a
23 summary of the article on it. I'm sorry, I don't have
24 all of the in-depth, but that would have been one of the
25 dynamics involved, yes.

1 Q I think what I'm holding is some exhibits from
2 Dr. Lemm's deposition. Have you spoken with Mr. Ernst
3 since Friday about this case?

4 A Yes.

5 Q Did he tell you anything about the testimony
6 that Dr. Lemm gave when we took his deposition in
7 Templeton on Friday?

8 A He had said that, as I recall -- again, these
9 are very short -- the drift of it was that Dr. Lemm had
10 attributed the patient's cause of death as digitalis
11 toxicity, if I recall correctly.

12 Q Is that it?

13 A That was the extent of the -- that topic, yes.

14 Q This is what we had marked as Exhibit 2 at
15 Dr. Lemm's deposition. An article by Vorpahl and Coe,
16 entitled, Correlation of Antemortem and Postmortem
17 Digoxin Levels.

18 Is this likely the article that Mr. Ernst sent
19 to you?

20 A It's possible, but it's not -- or a summary
21 thereof. This is not the exact article. Well, the
22 print on the page does not appear to be the same format
23 as what I was reading before, so...

24 Q Okay. Anything else you reviewed before
25 today's deposition?

1 A Not that I recall.

2 Q When was the last time you looked at a package
3 insert for a digoxin product?

4 A About a month ago.

5 Q Which product?

6 A What was digoxin.

7 Q Was it Lanoxin or Digitek?

8 A Well, basically, I looked up in Goodman and
9 Gilman, just happened to be an old copy lying around,
10 and I looked at it basically scanning through it for
11 that issue, as far as digoxin levels under different
12 circumstances, and I didn't really see anything.

13 Q How old are you?

14 A Fifty-nine -- 58. Will be 59 later this month.

15 Q Did you grow up in Central California?

16 A Yes.

17 Q Where?

18 A I was born in Paso Robles and grew up in that
19 area, rural Paso Robles.

20 Q And where did you go to medical school?

21 A University of California San Francisco.

22 Q Where did you do your internship and residency?

23 A Hennepin County Medical Center, which is
24 University of Minnesota, and an affiliate for internship
25 residency. Then cardiology fellowship at University of

1 Oregon.

2 Q Okay. Any other subspecialty fellowships?

3 A While I was at the University of Oregon, I did
4 a year of nuclear medicine.

5 Q Are you board certified in internal medicine?

6 A Yes.

7 Q Are you board certified in cardiology?

8 A Cardiovascular diseases, yes.

9 Q Are you board certified in anything else?

10 A There is a board of nuclear cardiology that
11 I'm -- I passed a board for that. It's not quite the
12 board of internal medicine, but, yes.

13 And then also in cardiology, um, I'm certified
14 as an -- in interventional cardiology.

15 Q How long have you been practicing cardiology in
16 the Templeton, California area?

17 A Since 1986.

18 Q Do you have any teaching appointments?

19 A No.

20 Q Your C.V. is probably going to be e-mailed here
21 to us, but have you published in the medical literature?

22 A May have authored one on something years ago,
23 but I can't remember.

24 Q Prior to the death of Dan McCornack in the
25 spring of 2008, had you ever met Mr. Ernst before?

1 A Yes.

2 Q Tell me how you know him.

3 A He attended Paso Robles High School as did I.

4 Q Were you in the same general class?

5 A He was a year ahead of me.

6 Q Okay. Have you known him in general since that
7 time?

8 A We've touched basis sporadically. Sometimes we
9 go 10, 20 years and not see somebody. Then sometimes
10 several times a year we cross informally.

11 Q Have you ever consulted with him on any cases
12 as an expert witness?

13 A No.

14 Q Has he written you any letters about this case?

15 A Um, there was one or two. Mainly just a
16 notification of this type of event.

17 Q Okay. How many times have you met with him in
18 person about this case before today?

19 A I'm sorry, I've been out of town for a week.
20 I'm a little bit fuzzy.

21 We met on Sunday, and before that was it phone
22 calls or did we meet in person? I think a phone call or
23 two and then one Sunday.

24 Q I don't get to take his testimony. I just want
25 to know your best memory.

1 A My best memory, once.

2 Q One time in person. And how many times on the
3 phone?

4 A Twice, as I recall.

5 Q And give me the general time frames of when
6 these phone or in-person meetings occurred.

7 A The first one, I believe, was August 21st. He
8 telephoned to inform me of the case, and the suit, and
9 some of the issues involved.

10 Q Are you talking about 2009 or 2008?

11 A No, 2009.

12 Q Okay.

13 A And I was unaware that a suit had become
14 involved with the situation so he enlightened me as far
15 as that goes.

16 And then one phone call had to do again with --
17 I don't -- I'm fuzzy. I don't remember all of the
18 details, but it had to do with the fact of -- the
19 question digitalis and digitalis toxicity and so on and
20 so forth.

21 Q Okay. Have you billed Mr. Ernst any -- for any
22 consultation time in this case?

23 A No.

24 Q Have you discussed Dan McCornack's case with
25 anyone other than Mr. Ernst?

1 A Not in particular, no.

2 Q Not in particular makes it sound like somebody
3 in general.

4 A Well --

5 Q I mean, obviously, you have to talk to your
6 staff about the fact that you're coming down here today
7 and logistical things like that. I'm talking about the
8 substance of the case.

9 A No.

10 Q Are you licensed to practice medicine in
11 California?

12 A Yes.

13 Q Are you licensed to practice medicine in any
14 other states?

15 A No.

16 Q Do you have continuing medical education
17 requirements?

18 A Yes.

19 Q I assume you keep up with those?

20 A Yes.

21 Q Have you taken any CME in the last five years
22 or so that have to do with drugs that exert
23 electrophysiological effects on the heart?

24 A Not specifically.

25 Q Do you have any subspecialty interests in

1 cardiology?

2 A As I mentioned, I'm certified in nuclear
3 cardiology and interventional cardiology. Um, basically
4 in general cardiology.

5 Q How much of your time do you think you spend in
6 interventional cardiology?

7 A Over the past couple years, very little. We've
8 brought in some partners who do most of that kind of
9 work, so I've faded in that. But your certification
10 carries through for ten years.

11 Q Do you see patients with heart failure?

12 A Yes.

13 Q Do you see patients with atrial fibrillation?

14 A Yes.

15 Q Let me ask you some general questions about
16 scientific analysis and methods. When you went to
17 medical school, I assume that one of the things that
18 they taught you was sort of how to think in a certain
19 way to approach the analysis of medical problems; is
20 that correct?

21 A Yeah.

22 Q Okay. And among those methods of assessing
23 scientific problems, did they teach you how to gather
24 reliable data in order to reach reliable and accurate
25 conclusions?

1 A Promise to do our best to do that, yes.

2 Q So ultimately, if you make a treatment plan,
3 it's based on as much reliable accurate data as
4 reasonably possible to get; correct?

5 A Yes.

6 Q So, for example, if an atrial fibrillation
7 patient came to you and you were suspecting and
8 analyzing whether they'd had myocardial infarction and
9 what heart disease they have, are there certain
10 laboratory studies available to you that you could
11 order?

12 A Yes.

13 Q Are there certain imaging procedures available
14 to you that you could order?

15 A That was mainly what I was thinking of when you
16 asked the other question.

17 Q So there's imaging.

18 When I said labs, I mean things like a CBC,
19 chemistry panels, INRs, cholesterol levels, things of
20 that nature.

21 A Yes.

22 Q And then, of course, as any physician, you
23 would take a history and do a physical exam; is that
24 right?

25 A That's correct.

1 Q As a cardiologist, do you rely from time to
2 time on electrocardiograms?

3 A Yes.

4 Q So in making a decision for this hypothetical
5 patient that I'm postulating about, you could gather as
6 much of that as was reasonable to order in order to make
7 a decision about diagnosis and treatment; correct?

8 A Ordinarily, yes.

9 Q And do you want that information, when you
10 order it, to be reliable?

11 A Yes.

12 Q So, for example, if there was an imaging center
13 that consistently produced poor quality MRIs, or
14 something like that, you might go to some other imaging
15 center that produced consistently high quality MRIs;
16 right?

17 A That's correct.

18 Q Hypothetically, if you were ever sued for
19 medical malpractice, you would certainly want the expert
20 on the other side to be using reasonable reliable data
21 in whatever criticisms they were going to make against
22 you; is that true?

23 A One would certainly hope so.

24 Q And you would hope they were using actual
25 scientific methods in coming to their conclusions;

1 right?

2 A That's correct.

3 Q Are you a member of any medical societies or
4 associations?

5 A The County Medical Society and American Medical
6 Association, American College of Cardiology.

7 Q What's the American College of Cardiology
8 Foundation?

9 A I don't know. There's several different
10 branches. There's a Political Action Committee, there's
11 a -- different ones under different names as far as
12 granting grants for education and research, and that may
13 be one of those.

14 Q Okay.

15 A I can't tell you exactly.

16 Q Do you have any special training in
17 epidemiology?

18 A No.

19 Q Pharmacology?

20 A No.

21 Q Pharmacokinetics?

22 A No.

23 Q Do you have any special training in toxicology?

24 A No.

25 Q Do you have any special training in nephrology

1 beyond basic --

2 A Internal medicine training.

3 Q -- internal medicine training?

4 A No, I do not.

5 Q Do you consider yourself to be an expert in
6 toxicology?

7 A No.

8 Q Are you still with Coastal Cardiology Group?

9 A Yes.

10 Q How many cardiologists are in that group?

11 A Twelve, 13. I think we just added one.

12 Q All right. How many years have you been with
13 Coastal Cardiology?

14 A Since 1986.

15 Q Do you have any military service?

16 A No.

17 Q When was the last time -- well, I'm sorry. Let
18 me withdraw that.

19 I asked you if you had any teaching positions
20 and you said no. Have you ever had a teaching position?

21 A No.

22 Q Do you subscribe to or regularly review any
23 particular medical journals?

24 A American College of Cardiology has a journal.
25 I read that one.

1 Q What's the name of it?

2 A Well, there's -- yeah. The Journal of American
3 Card -- College of Cardiology, and then there's also the
4 Journal of -- Journal of Cardiology. It's not the
5 correct name. I can't remember exactly what it is.

6 Q All right. Are there online resources that you
7 use?

8 A Yes.

9 Q Such as?

10 A There's one called Cardio Source Dot Com that
11 enables you to scan numerous journals.

12 Q Okay. Did you ever look at Cardio Source Dot
13 Com to find out anything about the Digitek recall?

14 A No.

15 Q Have you ever looked at Cardio Source Dot Com
16 for anything about digoxin toxicity?

17 A No.

18 Q What about diltiazem toxicity?

19 A No. I mean, certainly in years gone by I have,
20 but not in the past, recently.

21 Q Did you do any research on that particular web
22 site regarding anything to do with postmortem
23 redistribution of digoxin?

24 A No.

25 Q How often do you look at medical journals and

1 the current periodical medical literature?

2 A Probably several times a week.

3 Q And then, on top of that, you get the CME
4 requirements; right?

5 A Yeah.

6 Q How many hours of CME are you required to take
7 either on an annual basis or every two years?

8 A It would be 25 a year.

9 Q Twenty-five hours a year?

10 A Yeah.

11 Q Is it your understanding that -- well, withdraw
12 that.

13 Why do you spend so much time keeping current
14 in the journals and keeping up with your CME?

15 A Cardiology has had a tremendous growth, since
16 I've been in practice certainly. And on one hand the
17 knowledge that you have from the past counts for a lot.

18 On the other hand, new knowledge is added all
19 of the time. I think I learn as much in conversations
20 with other physicians that are experts in whatever
21 particular area the patient has.

22 I have a number of friends that are specialists
23 in different areas, electrophysiology, interventional
24 cardiology, that often have information far before the
25 journals do. That's probably one of my greatest sources

1 of education.

2 Q Okay. I think a couple of things you were
3 saying in there is that medicine advances quickly and
4 it's important to keep up with those changes; correct?

5 A Yes.

6 Q Is that part of the reliability of data that I
7 asked you about before? You want to make sure the data
8 you're relying on is current?

9 A Yes.

10 Q Okay. Do you have the PDR in your office?

11 A Yes.

12 Q Have you ever been a consultant to a
13 pharmaceutical company?

14 A No.

15 Q Do you know what an adverse event report is?

16 A I've heard of them. I don't know all of the
17 details of them.

18 Q Have you ever made an adverse drug event report
19 or an adverse event report to a pharmaceutical company?

20 A Not that I recall.

21 Q Do you prescribe medications -- I'm sorry.
22 Withdraw that question.

23 Do most prescription medications have some
24 risks?

25 A In general, yes. But not absolutely.

1 Q Okay. Do you prescribe medications that carry
2 risks up to and including death?

3 A Yes.

4 Q Does that include calcium channel blockers?

5 A Yes.

6 Q Does it include digoxin products?

7 A Yes.

8 Q And when you make a decision to prescribe such
9 a drug, I assume you are making an analysis that the
10 benefits for your patient out -- exceed the risks to
11 your patient?

12 A Yes.

13 Q Do you give handouts to your patients regarding
14 the medications that they are taking for their heart?

15 A Sometimes yes; sometimes no. Some don't want
16 them. Some do. And we don't ordinarily do it because
17 the pharmacists are generally pretty good with that.

18 Q Okay. But, so I think what you're telling me
19 is for something like diltiazem or digoxin, you would
20 rely on the pharmacy to hand out the actual paper
21 regarding those --

22 A That's correct.

23 Q -- drugs?

24 What about in general for a disease like atrial
25 fibrillation, do you hand out information about that?

1 A That's available. I personally don't do it
2 routinely. I usually have an extended verbal
3 conversation with the patient and family.

4 Q Okay. Do you keep any cardiology texts in your
5 home or office medical library?

6 A Numerous ones, yeah. We have -- I mean,
7 ultrasound and interventional cardiology, and then the
8 general Brown Wall and those other type of cardiology
9 texts that are around the office all of the time, yeah.

10 Q Do you have Hurst's Cardiology?

11 A That's one of them. It ranks with Brown Wall,
12 yes.

13 Q When you say "ranks with," they are widely
14 regarded as some of the most reliable general cardiology
15 textbooks?

16 A That's right.

17 Q Do you keep any toxicology books?

18 A Not specifically, no.

19 Q Other than the PDR about drugs, do you keep any
20 others besides perhaps Goodman and Gilman?

21 A No.

22 Q Do you know what edition of Goodman and Gilman
23 you happened to consult within the last couple of months
24 about digoxin?

25 A It's probably been like ten years or older,

1 but, no.

2 Q In general, does renal function diminish with
3 advancing age?

4 A Yes.

5 Q In your cardiology patient population, have you
6 found it to be true that diseases like hypertension can
7 adversely impact renal function?

8 A Yes.

9 Q Have you also found it to be true in your
10 practice that a number of your patients need a number of
11 different medications to control various disease states
12 that they have?

13 A Many times, yes.

14 Q And is that called polypharmacy?

15 A That word could be applied I suppose, yeah.

16 (Discussion held off the record.)

17 BY MR. MORIARTY:

18 Q If a patient has underlying renal
19 insufficiency, does it increase the risk that they can
20 get an adverse drug event from drugs that are typically
21 cleared by the kidneys?

22 A Yes.

23 Q Is diltiazem cleared by the kidneys?

24 A I believe in part that it is.

25 Q Digoxin is cleared by the kidneys?

1 A Yes.

2 Q So, renal insufficiency has the potential to
3 increase the risk of digoxin toxicity?

4 A Yes.

5 Q How often do you prescribe cardiac glycosides
6 for your own patients?

7 A It depends if they need them or not. Commonly.

8 Q I'm sorry. My question really was not very
9 good.

10 In your practice, overall, I assume it's common
11 for you to prescribe cardiac glycosides?

12 A Yes.

13 Q Is digoxin far and away the one you prescribe
14 the most?

15 A Yes.

16 Q Do you have any estimate of the percentage of
17 your patients that are on digoxin products?

18 A I guess between 10 and 20. That is a guess.

19 Q Have you been prescribing digoxin for other
20 cardiac glycoside products for all of your cardiology
21 career?

22 A Yes.

23 Q When was the last time you looked at a
24 diltiazem label?

25 A Sometime within the past year, but not

1 recently.

2 Q Was it anything to do with this case or was it
3 just in the general course of your practice?

4 A General course of practice.

5 Q Is diltiazem a calcium channel blocker?

6 A Yeah.

7 Q Now, in Mr. McCornack's case, what was the
8 purpose for the prescription of diltiazem?

9 A To reduce the rate of the ventricular response
10 to the atrial fibrillation.

11 Q In short, rate control?

12 A Yeah, ventricular rate control, yes.

13 Q For Mr. McCornack, would a secondary benefit be
14 antihypertensive?

15 A Yes.

16 Q Are you the one who prescribed the diltiazem
17 products for him?

18 A I can't remember. I know he's been on it for a
19 decade, and I'm not sure who initiated the drug.

20 Q Do you know whether he was on any separate
21 antihypertensives?

22 A I'd have to look at the chart.

23 Q You're welcome to do that at any point today.

24 A And I'm not sure when he was last in our
25 office, but there's a note for November 2007 he was --

1 he was not on either antihypertensive medications.

2 Q Okay. It says in the diltiazem label under the
3 warning section that concomitant use of diltiazem with
4 beta blockers or digitalis may result in additive
5 effects on cardiac conduction.

6 Is that consistent with your experience?

7 A Yeah.

8 Q Is it your experience that diltiazem can
9 elevate serum digoxin levels?

10 A Yes.

11 Q I'm sorry, that's a "Yes"?

12 A Yes.

13 Q From your records, and any other information
14 you have about Mr. McCornack, was he prescribed any
15 medications with quinine or quinidine in them?

16 A Not to my knowledge.

17 Q Other than tonic water, are there commonly
18 consumed food or beverage products that contain quinine?

19 A I'm not aware of them.

20 Q Have you seen the postmortem blood sample
21 results from the NMS Laboratory in Pennsylvania
22 regarding Mr. McCornack?

23 A Yes.

24 Q Did you notice that there were trace levels of
25 quinine in his blood?

1 A Yes.

2 Q Do you have any opinion to a reasonable degree
3 of medical probability as to what caused that?

4 A I can offer no insight.

5 Q In the Adverse Reaction section of the
6 diltiazem label, it indicates that patients can get
7 bradycardia first degree A.V. block, among others,
8 including arrhythmias, bundle branch block, hypotension,
9 palpitations.

10 Are those adverse reactions consistent with
11 your experience?

12 A Yes. Well, some of them. I don't know that
13 I've seen bundle branch block. But I've seen the
14 others.

15 Q Okay. What sort of discussion would you have
16 had with Dan McCornack when he started as a patient on
17 digoxin?

18 A When I first met him, he had atrial -- bouts of
19 atrial fibrillation, where most of the time the
20 fibrillation was not present, but intermittently the
21 fibrillation rhythm could occur and be bothersome to
22 him.

23 When we first initiated digoxin, it was done
24 with the hope of having some prevention of the atrial
25 fibrillation in the first place. And, secondary to him,

1 when he did have atrial fibrillation, the heart would go
2 -- the ventricular response would be relatively rapid,
3 and it was uncomfortable to him.

4 So, generally, we spoke about, first of all,
5 trying to prevent the fibrillation, and second of all,
6 when it did occur, to lessen his symptoms from that.

7 Q Okay. And what discussion would you typically
8 have with a patient like Mr. McCornack about the risks
9 and complications of digoxin therapy?

10 A In his case, I'd tell him that the ordinary
11 risk of life and death are minimal as best we can tell,
12 in the ranges we would intend to use them.

13 In some patients whose heart rate has a
14 tendency to go slow, we do have to worry about slow
15 heart rates.

16 In his case, it was always going faster than
17 what was comfortable or good. So I'd tell him to be
18 aware of things becoming very slow, whatever. But that
19 was not much of an issue on him because of the rapid
20 ventricular response.

21 Q What would you typically tell him to look for
22 as adverse reactions to a digoxin product?

23 A Well, in terms of the heart rate too fast which
24 he was aware of. Too slow would be dizziness,
25 light-headedness, slower pulse, shortness of breath,

1 tiredness, fatigue, lack of energy.

2 The digitalis toxicity, we told people about
3 the nausea, the lethargy.

4 You know, back in the old days when we had the
5 mixed, we would sometimes have more, call it change of
6 vision, that sort of thing. In this case, because we
7 checked the levels and that sort of thing, it was really
8 a nonissue.

9 We usually explain the fact that the digitalis
10 doesn't act right now. I mean, you could take a pill
11 right now, it may not have an effect for -- well, in
12 starting off pills it takes four or five days for the
13 level to become therapeutic.

14 So we have some people that would have a very
15 rapid heart rate if you take a drug such as Allopurinol
16 or Inderal, which is rapid onset, rapid acting. If you
17 take a pill now, you should see the results within a
18 couple hours.

19 Where with the digitalis, we don't expect
20 immediate results. It takes a while.

21 Q Okay. For atrial fibrillation patients, do you
22 have a particular target range for a serum digoxin level
23 that you're looking for?

24 A Mainly we try to avoid going above 2.0. The
25 effect of digitalis in some people is that they can have

1 slow heart rates at a far lower level. These are the
2 drugs, the limitations of its use are generally
3 approaching the level of 2.0 or also slower heart rate.

4 Q So you don't have some floor where you are
5 trying to keep your patients at .5 to 1.5 or something
6 like that?

7 A No. Because some people would be going way too
8 slow even a level of .5.

9 Q And have you seen instances where different
10 laboratories have different normal ranges for digoxin?

11 A Yes.

12 Q So typically I see .8 to 2.0. What other
13 ranges have you seen?

14 A I don't recall any that would -- again, the
15 uses of the digitalis, some of them can be for
16 congestive heart failure where you're looking for
17 anatrohic effect or increased contractility of the
18 cardiac muscle, in which case I would then pay more
19 attention to be sure that I have the lower number in a
20 working range type of thing. That's unusual for us
21 because other drugs involving. We try to keep things
22 below the 2.0. But yes, different labs reported
23 different numbers over the years, and I can't cite you a
24 chapter and verse.

25 Q So, if you are looking at a patient -- I'm

1 sorry. Withdraw that question.

2 Were you practicing when the .50 milligram dose
3 was still commercially available?

4 A Likely.

5 Q Were you a practicing cardiologist in the early
6 to mid '90s?

7 A Certainly.

8 Q Okay. Now, from time to time, have you
9 diagnosed digoxin toxicity in your own patients?

10 A Yes.

11 Q How many times do you think you've done that in
12 your career?

13 A In terms of chemical digitalis toxicity as far
14 as digitalis levels being excessive of 2.0, it's been
15 probably dozens.

16 In terms of them presenting in the emergency
17 room with clinical digitalis toxicity and rhythms of
18 that, it would probably be five to ten.

19 Q Okay. Let's get -- make sure we're
20 communicating on the same wavelength.

21 If somebody has a serum digoxin concentration
22 while they are alive, of greater than 2.0, do you
23 automatically diagnose them with digoxin toxicity?

24 A If you're -- if you're talking about a clinical
25 syndrome of symptoms and signs, not necessarily.

1 Q Okay. Isn't digoxin toxicity a syndrome of
2 clinical signs and symptoms?

3 A It can manifest in a number of different ways.
4 Not always the same in every patient.

5 Q Is digoxin toxicity considered a laboratory
6 diagnosis?

7 MR. ERNST: Objection.

8 Just because I made an objection doesn't mean
9 you can't answer the question. It means I've made an
10 objection for a court to determine later. If you can
11 answer, go ahead and answer the question.

12 THE WITNESS: Yeah. I guess I would personally
13 consider a person to be digitalis toxic if they had a
14 level above 2.0 and then there becomes a variation of
15 that.

16 I've had people who did have digitalis levels
17 higher than that but did not manifest the clinical
18 symptoms as far as more adverse cardiac arrhythmias, or
19 nausea, vomiting or visual changes, but I would consider
20 them to be -- again as a relative term, we have people
21 with digitalis levels come back in different ranges. If
22 they are mildly elevated I don't know that I would call
23 it necessarily toxic. How you transition from mildly
24 elevated to toxic, I guess that would be somewhat
25 arbitrary.

1 BY MR. MORIARTY:

2 Q Well, just because somebody has an elevated
3 serum digoxin concentration does not mean they have
4 clinical signs and symptoms of digoxin toxicity?

5 A That's correct, yes.

6 Q Just because somebody has elevated serum
7 digoxin concentrations does not necessarily mean that
8 they have arrhythmias that would be detected on an
9 electrocardiogram?

10 A That's correct.

11 Q And certainly just because somebody has an
12 elevated digoxin concentration is not in and of itself
13 fatal; right?

14 A That's correct.

15 Q Is there any serum digoxin concentration that
16 you're aware of that, in all cases, is fatal?

17 A No. I guess I've not seen digoxin levels of
18 ten, but...

19 Q So, for the most part, if you were going to
20 make a complete diagnosis of digoxin toxicity, would you
21 want to have, optimally, a serum digoxin concentration,
22 some clinical evidence and electrocardiographic
23 evidence?

24 A Yes. In my training, I -- in the earlier
25 years, we had use of digitoxin and sometimes even more

1 of a mixture digitalis glycosides.

2 It seems to me, my understanding is that the
3 symptoms of the nausea, visual changes, those types of
4 things, were much more common in the patients that had
5 the nondigoxin, or the additional more complex
6 associated derivatives.

7 With the digoxin by itself purified, a lot of
8 times we don't see the nausea or things like that. We
9 just see the patient who is there because of arrhythmia
10 type problems. They don't always manifest the secondary
11 visual or G.I. symptoms.

12 Q Are these people who you are seeing by
13 coincidence and they have an abnormal rhythm, or do they
14 have some clinical --

15 A They come to the emergency room because they
16 are feeling sick because the heart is racing or going
17 too slow.

18 Q Okay. Is digoxin toxicity relatively common?

19 A No.

20 Q Is it a well-known phenomena among physicians
21 like you who prescribe the drug?

22 A Yes. And I think part of it dates back to when
23 I was in medical school in the seventies. There were
24 articles coming out that stated they felt a third of
25 the -- or actually 20 percent of hospital admissions

1 were related to digitalis toxicity. That was for the
2 pre-digoxin era.

3 Q To the best of your understanding, patients can
4 get digoxin toxicity clinically, or elevated levels even
5 though they are on normal doses of the drug?

6 A Yes.

7 Q How come patients can get elevated levels or
8 digoxin toxicity even at normal doses?

9 A We don't always know why. There are certain
10 other medicines which can adversely affect renal
11 function or some other illnesses can intervene.
12 Sometimes it just seems to happen.

13 We're never completely sure what doses the
14 patients are taking at home. There can be some
15 unexpected, as you mentioned, renal dysfunction that we
16 don't have awareness of.

17 Q Are you done with your answer?

18 A (Witness nods head up and down.)

19 Q I don't want to cut you off.

20 A Yes.

21 Q So to go at this another way, things like
22 illness or other medications that would reduce renal
23 clearance could increase digoxin levels; correct?

24 A Yes.

25 Q Other medications can do that through one

1 mechanism or another; is that true?

2 A Yes.

3 Q Things that decrease --

4 A Glomerular filtration rate.

5 Q That goes into renal insufficiency; correct?

6 A Yes.

7 Q Things -- drugs or illnesses that would reduce
8 the distribution of a drug throughout the body might
9 drive levels up, is that true, or do I have that
10 backwards?

11 A Digitalis is transported and taken up by
12 muscle, and someone been on a chronic dose for a long
13 time and undergoes a major muscle wasting illness, I
14 guess that can do something.

15 Q Volume depletion; correct?

16 A (Witness nods head up and down.)

17 Q Okay. And electrolyte abnormalities can do
18 that; is that right?

19 A They can be associated with digitalis toxicity.
20 They don't necessarily -- anything that could affect the
21 renal function, nonsteroidal antiinflammatory agents,
22 diuretics, other medicines can change how it is.

23 Q And I think you said sometimes you just don't
24 know why a level is elevated; is that right?

25 A That's correct.

1 I guess, again, you're getting my clinical
2 gestalt from years, but commonly it -- more commonly
3 it's in the elderly person who has multiple things going
4 on and multiple drugs coming and going, and has a
5 significant impaired renal dysfunction in the first
6 place.

7 Q Do you typically draw serum digoxin levels on
8 your patients who are chronically taking --

9 A Yes.

10 Q -- the drug?

11 A (Witness nods head up and down.)

12 Q How often do you tend to draw those levels?

13 A We usually draw them much more frequently as
14 we're getting the drug set up and into use. Once
15 they've been, if you will, stabilized in a pattern, we
16 would check them several times a year.

17 Q Okay. And then is there an optimal time to
18 draw the serum digoxin level following the last dose?

19 A In general, we try to have all of the digoxin
20 levels drawn at least seven hours after the last oral
21 dose.

22 Q Why?

23 A Levels drawn earlier than that may be
24 elevated.

25 Q Because it has not distributed to steady state?

1 A That's correct. Taken in the stomach, being
2 transported by the bloodstream throughout the muscle
3 cells. For a while, it can be elevated.

4 Q Under that window of time it's still too close
5 to the peak plasma level; correct?

6 A It may be, yes.

7 Q Do electrolyte imbalances, particularly
8 potassium, play an important role in the etiology of
9 digoxin toxicity?

10 A Yes.

11 Q Can potassium levels, whether elevated or below
12 the appropriate range, cause digoxin toxicity?

13 A They can certainly enhance it.

14 Q Okay. Is the same true with calcium?

15 A Yes.

16 Q Now, can -- I'm probably not going to get this
17 right, but can elevated potassium levels cause
18 arrhythmias?

19 A Yes.

20 Q Life threatening arrhythmias?

21 A More commonly it's cardiac slowing and
22 standstill. But, yeah, slower rhythms.

23 Q And can abnormal calcium levels do the same
24 thing?

25 A To some extent, yes.

1 Q Would BUN, creatinine and/or the estimated
2 glomerular filtration rate be some of the measures you
3 would look at in determining renal sufficiency?

4 A They are the main standards.

5 Q Okay. If a patient has an elevated BUN or
6 creatinine, or low GFR or some combination of those,
7 that would be at least a potential sign of renal
8 insufficiency which could then increase the risk of
9 digoxin toxicity; correct?

10 A Yes. Although I think Mr. McCornack is a
11 pretty muscular guy, and sometimes young muscular
12 people, because the BUN, creatinine for those can be --
13 frail, elder women can be low levels. Where young,
14 muscular guys can kind of be at the upper end.

15 Q Do you know whether Alli -- he was on a gout
16 medication, Alli --

17 A Allopurinol.

18 Q Allopurinol. Do you know whether that can
19 increase digoxin levels?

20 A I don't know specifics.

21 Q Do you know if it decreases renal clearance?

22 A It's not a major player. It may alter it
23 slightly.

24 Q Was Mr. McCornack on any diuretics?

25 A Not to my knowledge.

1 Q Okay. Your staff was kind enough to e-mail
2 your C.V.; correct?

3 A Correct.

4 MR. MORIARTY: Can you mark that as Exhibit 1.

5 (Defendants' Exhibit 1 marked for
6 identification.)

7 BY MR. MORIARTY:

8 Q Is this your C.V.?

9 A Best I can tell, yes.

10 Q Are there any significant speeches,
11 publications or research grants that are not --

12 A No.

13 Q -- on that C.V.?

14 A No.

15 Q All right. In your -- in your cardiology
16 practice, do you have other patients who are claiming to
17 have suffered injuries as a result of taking Digitek, to
18 your knowledge?

19 A I think over the past year or two a couple have
20 popped up. But when we check levels, either we're far
21 enough from the time the pills had been used or the
22 levels were drawn that were not of concern. So nothing
23 more than one of the number of other things that popped
24 up as questionable circumstances.

25 Q Have you looked at any statements online about

1 what the FDA is currently saying about the Digitek
2 recall and the likelihood that Digitek tablets caused
3 harm to patients?

4 A No.

5 Q Are you aware of any published medical
6 literature which says that digoxin products themselves
7 cause renal failure?

8 A Not in usual doses.

9 Q Okay. All right. Let's talk about
10 Dan McCornack a little bit here. May I see that chart?
11 You had your staff e-mail your chart up here; right?

12 A Looks like part of it, but, yes.

13 Q Do you keep all of your medical records
14 electronically?

15 A Yes.

16 Q My notes -- my notes indicate that you actually
17 saw Mr. McCornack going back to something like 1992, but
18 the medical record that I brought with me from Ohio only
19 goes back to about 1998 or so.

20 A That may have been when the medical records was
21 initiated in our office. The previous paper notes
22 didn't always get carried over.

23 Q What would have happened to previous paper
24 notes that were kept in his chart prior to the creation
25 of an electronic record?

1 A They were ultimately destroyed.

2 Q Do you know when they were destroyed?

3 A Seven or eight years afterwards, I guess.

4 Q Do you have independent memory of when
5 Dan McCornack started with your office as a patient?

6 A No. There was one note in -- well,
7 Dr. Roger Winkle's note mentioned that he's been a
8 patient of Dr. David Harvey, who had been with our
9 group. He'd joined our group at some point in the past.
10 Again, I can't tell you the year. That would have
11 predated that as well.

12 Q Okay. When did Dr. Harvey retire?

13 A He actually left the group. I believe he's
14 still in practice in Texas. I don't remember the year.

15 Q Now, according to the records Mr. McCornack
16 had, he was diagnosed with atrial fibrillation at about
17 the age of 22. Is that consistent with your memory?

18 A Yes.

19 Q What is the significance, if any, of such a
20 early onset of A. fib?

21 A It happens. And going back to your original --
22 one of your earlier questions, we usually will check the
23 patient out with cardiac ultrasound. Check the thyroid
24 panel, look for any other signs of underlying problems
25 that may cause the fibrillation. In his case, no other

1 cause was found. It just happens sometimes.

2 Q Is it unusual?

3 A Uncommon, certainly, yes. Most 21 year olds,
4 22 year olds don't have atrial fibrillation.

5 They do have other -- well, never mind. They
6 do have other fast heart rhythms, but on occasion.

7 Q Because he had to live a long time with atrial
8 fibrillation, did it increase the risk of him having
9 sudden cardiac death?

10 A Relatively small.

11 Q Why relatively small?

12 A Well, as long as the fibrillation -- I think if
13 you take 100,000 people with atrial fibrillation and
14 100,000 people without, that being the only variable,
15 there's probably a very slightly higher rate of
16 complication; strokes and so forth than that. But if
17 the heart is otherwise normal in its structure and other
18 factors, the difference is very, very small and
19 difficult to measure.

20 Q Okay. Is sudden cardiac death a risk of atrial
21 fibrillation?

22 A Ordinarily, if that's the only problem, the
23 answer is no.

24 Q Not a risk at all? I mean, elevated above the
25 general population?

1 A There's a very small chance of having clots
2 develop in the atrium. If those clots break lose and go
3 someplace to the heart itself or the brain, that could
4 cause cardiac death, but that's very unusual.

5 Q Did Mr. McCornack have hypertension?

6 A Yes, mild.

7 Q Do you have an opinion as to the cause of his
8 hypertension?

9 A Ordinarily, it's essential, which means it
10 happens.

11 Q Well, is it genetic or is it based on his
12 weight or don't you -- is there no way to know?

13 A Um, your -- most people are born with a hat
14 size, a shoe size, and you have a blood pressure size.
15 A certain percentage of peoples blood pressure is higher
16 than what is the desired amount, which would be 140 over
17 90 or dropping 130 over 80. Statistically, as the blood
18 pressure goes higher those people are more likely to
19 have vascular injury as the years go by. For years,
20 they thought it might be due to renal artery obstruction
21 or things like that. But very often you look and there
22 are no causes. The blood pressure is just higher than
23 what is in their best interest.

24 Q As a result was Mr. McCornack felt to have
25 arterial sclerotic heart disease?

1 A There was no evidence of that.

2 Q Ever?

3 A Well, most of us will have some plaquing in our
4 arteries. We don't like to think about it, but we do.
5 As far as that progression to the point of angina
6 pectoris or myocardial damage, there was no clinical
7 evidence of that.

8 Q Did you ever advise Mr. McCornack to lose
9 weight?

10 A Yep.

11 Q Most visits?

12 A Half the time.

13 Q He met the medical definition of obesity, did
14 he not?

15 A I don't know what criteria he used. In my
16 mind, he was not obese. He was certainly heavier than
17 ideal.

18 Q Why did you advise him to lose weight?

19 A Well, he also -- his lipids were elevated, his
20 cholesterol, those types of things. Ordinarily, people
21 do better to have lower weight and lower cholesterol.

22 Q Did he report to you on a number of occasions
23 that he had a lot of stress related to his work?

24 A On occasion.

25 Q Did you advise him to stop chewing tobacco?

1 A Yes.

2 Q Why?

3 A Well, the incidence of oral lesion is higher
4 with tobacco products.

5 Q To your knowledge, does oral tobacco product --
6 I mean chewing tobacco products pose any increased
7 cardiac risk?

8 A No.

9 Q Are you familiar with the new 2007 ACCFAHA
10 guidelines on the management of atrial fibrillation?

11 A Yes.

12 Q I'm sorry?

13 A Yes.

14 Q If you were to classify Mr. McCornack's atrial
15 fibrillation, how would you have classified it in 2007
16 when you last saw him, which I believe was in November?

17 A I would classify him as idiopathic atrial, lone
18 atrial fibrillation. Atrial fibrillation, not
19 necessarily in conjunction with other major risk
20 factors.

21 Q Was it recurrent?

22 A It had begun as being rare and infrequent. Had
23 become recurrent, and then had progressed into, we
24 believe, chronic atrial fibrillation.

25 Q Is chronic pretty much the same as permanent

1 and persistent?

2 A Yes.

3 Q Was it paroxysmal?

4 A That would have been the intermittent phase.

5 Q Was it symptomatic?

6 A Yes.

7 Q What were his A. fib symptoms?

8 A Initially, when it happens, go into a sudden
9 change from a stable rhythm to a fibrillation. People
10 feel the palpitations. Sometimes they can have some
11 chest discomfort, sometimes sweaty. At times in the
12 earlier years he would have things such as that. Later
13 on he noticed the palpitations, didn't have the chest
14 pains so much. And certainly as it became chronic, he
15 noticed he had less exercise tolerance. He couldn't
16 perform as well physically as originally.

17 Q Did he complain of fatigue?

18 A Yes.

19 Q So, his diltiazem was for rate control with his
20 secondary benefit of antihypertensive.

21 What was the focused purpose of the digoxin
22 prescription?

23 A Rate control.

24 Q Is it common for you as a cardiologist to
25 prescribe more than one drug for rate control in atrial

1 fibrillation patients?

2 A Not unusual. I guess maybe 20 percent.

3 Q Well, why would -- why the need for two
4 different drugs for rate control in Dan McCornack's
5 A. fib?

6 A Um, it relates back to each individual and the
7 properties of atrial ventricular node. Its the ability
8 to conduct the fibrillation signals through the
9 ventricles.

10 Some people's A.V. node is able to conduct much
11 more rapidly than others. Others are slower. He
12 happened to have a relatively rapid rate of conduction
13 to the atrial ventricular node.

14 Q Is that a way of saying he really needed
15 more umph or more therapy to control his A. fib?

16 A I guess I wouldn't use the word "umph." He
17 needed more breaks on this.

18 Q More breaks. Okay. That's good.

19 A More retarding.

20 Q Okay. And sometimes it's more efficacious to
21 combine two different therapies than to just give higher
22 doses of one; correct?

23 A Their affects can be additive. And there are
24 limitations on how much diltiazem you want to give and
25 how much digoxin you want to give.

1 Q Okay.

2 MR. ERNST: We've been going an hour. Are you
3 uncomfortable? Do you want to take a break?

4 THE WITNESS: So far so good.

5 MR. ERNST: Okay.

6 MR. MORIARTY: Could you mark this as Exhibit
7 2, please?

8 Q Dr. Von Dollen, I've had this marked as
9 Exhibit 2. That's NMS Lab's report dated June 24th,
10 2008, regarding a postmortem blood specimen for
11 Dan McCornack.

12 (Defendants' Exhibit 2 was marked
13 for identification.)

14 BY MR. MORIARTY:

15 Q Have you ever seen that before?

16 A Yes.

17 Q Did you receive that from Mr. Ernst?

18 A Yes.

19 Q How long ago did you receive it from Mr. Ernst?

20 A Two days ago. Somewhere over the weekend. He
21 showed it to me. I've not received a copy of it.

22 Q But you didn't see this until very recently?

23 A That's correct.

24 Q I'd like you to go to the second page. Item
25 Number 2 is a statement by NMS Labs from their computer

1 system, about diltiazem. Do you see that?

2 A Yes.

3 Q And, at least according to what NMS Lab says,
4 the last sentence says, "In addition, diltiazem is
5 reported to undergo postmortem redistribution with an
6 average heart blood/femoral ratio of 2.6."

7 Do you see that?

8 A Yes.

9 Q Do you have any reason to disagree with that?

10 A No.

11 Q And at least according to NMS Labs,
12 Mr. McCornack's postmortem diltiazem level of 630 would
13 be three or more times the normal antemortem diltiazem
14 level; is that fair?

15 A 630 -- I'm sorry. You were saying that the 630
16 would be three times?

17 Q The normal antemortem diltiazem level, at least
18 as reported by NMS?

19 MR. ERNST: I'm sorry, I didn't mean to
20 interrupt you, Counsel. I thought you were finished.

21 Objection. Once again, I'm making an objection
22 for the record. His question stands and you can answer
23 it if you can.

24 THE WITNESS: Yeah, I mean, if you accept the
25 therapeutic blood levels between 50 and 200, and this

1 was 630. That would be three times that.

2 BY MR. MORIARTY:

3 Q Okay. Do you have some other understanding of
4 what therapeutic diltiazem levels are?

5 A No.

6 Q Okay. Would -- if this lab information was
7 presented to you when Mr. McCornack was alive and you
8 looked at it and his level was 630, would you say that
9 he was diltiazem toxic?

10 MR. ERNST: Objection.

11 THE WITNESS: Um, not ordinarily.

12 BY MR. MORIARTY:

13 Q Okay. Why?

14 A Different, quote, unquote, therapies are
15 reported for different situations, and I would have to
16 ask them if there are other situations in which other
17 numbers might be acceptable.

18 If it's for use of hypertension, if it's used
19 for rhythm control, if it's used for vaso spastic
20 angina. I don't know if there are other values that
21 have been thought to be acceptable under different
22 circumstances.

23 Q Part of what you are telling me is that the
24 number 630 doesn't tell the whole story; correct?

25 A That's correct. And the other part of the

1 question is what's thought to be a quote, unquote,
2 therapy, what is then, if you will, the therapeutic
3 index or the toxic range.

4 Q And in order to assess the meaning of this
5 number, you'd want to know how reliable it is as a
6 predictor of a toxic level in a living patient; correct?

7 A That's one side is a therapy, therapeutic, the
8 beneficial effect, what things you have to go to before
9 you have adverse effects.

10 Q Okay. Did you ever diagnose Mr. McCornack with
11 diltiazem toxicity?

12 A No.

13 Q When you looked at this report when you were
14 talking with Mr. Ernst, did you talk about the diltiazem
15 level?

16 A It was mentioned as it went by, but no
17 conversation led after that.

18 I guess I just have to say, in clinical
19 practice we have a lot of people on diltiazem over the
20 years, and ordinarily within the prescribed dosage
21 levels we've not really encountered diltiazem toxicity.

22 Q When you see an elevated level like this in a
23 in a postmortem blood specimen, it doesn't automatically
24 lead you to conclude that he took an excessive dose,
25 does it?

1 A That's correct.

2 Q Are atrial fibrillation patients at risk of
3 clots?

4 A Yes.

5 Q And, typically, atrial fibrillation patients
6 get an anticoagulant, do they not?

7 A Over the years they have. Under recent
8 guidelines and in many situations it was lone atrial
9 fibrillation they don't get anything more than aspirin.

10 Q Why didn't Mr. McCornack get an anticoagulant?

11 A Again, he may have had mild hypertension, but
12 there would be no other major structural heart disease.
13 He was in the lower risk of clots in the first place,
14 and therefore he didn't get the Coumadin.

15 Q Okay. Did he ever express to you some
16 hesitance to take Coumadin because of his lifestyle?

17 A Yes.

18 Q Did you ever sign a death certificate for
19 Dan McCornack?

20 A Not that I recall.

21 Q Were you ever asked to by the Santa Cruz County
22 Coroner?

23 A Not that I recall.

24 Q Do you remember ever having any discussion with
25 the Santa Cruz County Coroner yourself?

1 A Not that I recall.

2 Q Were you aware that your office faxed medical
3 records regarding Dan McCornack to the Santa Cruz County
4 Corner's office at their request after he died?

5 A Well, in reviewing the chart today, I saw the
6 slip, but I can't remember at the moment if the call
7 came in, if I was in composition of that then or not.

8 Q Now, within weeks of Mr. McCornack's death, the
9 coroner issued an autopsy report, and then there was a
10 death certificate associated with that. Are you aware
11 of that?

12 A I have heard that it happened, but I don't know
13 the timing or...

14 Q Have you ever seen the original autopsy
15 report --

16 A Yes.

17 Q -- or death certificate for Mr. McCornack?

18 A Yes.

19 Q I deposed Dr. Mason, the coroner, last Thursday
20 afternoon in San Jose, and the day before, in other
21 words, Wednesday of last week, he issued an amended
22 death certificate and autopsy report. Have you seen
23 those amended reports?

24 A No.

25 Q Do you know what the new articulated cause of

1 death sequence was?

2 A I believe the digitalis intoxication was
3 mentioned on that. Again, that's word of mouth what
4 Mr. Ernst mentioned.

5 Q Do you know what the basis was for Dr. Mason
6 changing his opinions and his reports a week ago?

7 A No.

8 Q Mr. -- the notes that we have put together
9 regarding Mr. McCornack indicate that by 1994 and onward
10 he was pretty consistently getting .50 milligrams of
11 digoxin a day split between 2.25 milligram doses. Are
12 you aware of that?

13 A Yes.

14 Q And whether or not you are the one who actually
15 started him on that dose, you continued him on that dose
16 for some years; correct?

17 A I likely was the one who started him on it
18 because we tried some other medications in place of
19 those earlier that he hadn't tolerated.

20 Q Such as Androderm?

21 A Yes, and also beta blocker.

22 Q So what was the rationale behind the dosing
23 regimen of .25 twice a day?

24 A Ordinarily, as long as you get the dose within
25 24 hours, the effect should be relatively the same.

1 Some people feel better having the split dose.

2 There's many antihypertensive agents that are
3 supposedly covered 24 hours quite well, don't do quite
4 as well for 24 hours. Digitalis covers long enough that
5 you wouldn't expect that. But diltiazem had to go twice
6 a day. It's just easy to do digitalis a day as well.

7 Q Was he on diltiazem doses per day?

8 A I have to check the record. At different times
9 he was and other times he was wasn't, I believe.

10 Q Let's just go to 2007.

11 A Yes, he had the 300 and then he had the 180.

12 Q Same exact drug, but just two different doses?

13 A Right. They are supposed to be long acting to
14 cover 24 hours as well, but sometimes they don't
15 completely cover a 24-hour period as well if you give it
16 in divided dosage.

17 Q Okay. Now, do you remember hospitalizing
18 Mr. McCornack at Twin Cities in 1994?

19 A I believe he was admitted for a cardioversion,
20 but I can't remember more than that.

21 Q Would it be likely that during an admission for
22 cardioversion he would have been administered I.V.
23 digoxin products?

24 A Not usually, but possible.

25 Q Okay. At any point, to your memory or from

1 whatever records you have available to you today, did
2 Mr. McCornack -- was he prescribed digoxin doses higher
3 than .5 per day?

4 A In my chart notes there was some mention of
5 trying a higher dose temporarily. But, ordinarily, I
6 wouldn't. I can't say for sure.

7 Q Okay. I'm just wondering if, during an
8 admission, perhaps he was given higher I.V. doses?

9 A Sometimes if a person comes in for a
10 cardioversion for atrial fibrillation, and the
11 cardioversion is done and the sinus rhythm is restored,
12 if we have concerns about loss of the rhythm again,
13 we'll sometimes give additional antiarrhythmic of sorts.
14 Which, if we thought a digoxin level was low, we could
15 possibly give him some I.V. digoxin as a one time deal
16 to help prevent the fibrillation from occurring.

17 Q I'm looking for a particular note in your
18 chart. Okay. Do you have your February 16, 2000,
19 office note with you? February 16, 2000?

20 A It's not in the sequence here. I can keep
21 looking if you'd like. Yes, here it is.

22 Q Okay. I'd like you to look at that note under
23 the Chief Complaints section.

24 Well, I'm sorry, first look at the Current
25 Medications. According to this, he's getting Lanoxin,

1 .25 milligrams, one tab BID. Do you see that?

2 A Yes.

3 Q And then under Chief Complaint, the third line
4 down, it says he doubled up on his Lanoxin.

5 A Uh-huh.

6 Q Do you remember this incident?

7 A Just vaguely, yes.

8 Q What does it mean in your History section when
9 it says he doubled up on his Lanoxin?

10 A Um, usually he would take a double dose of the
11 medication. And some people will do that as -- if they
12 feel the heart racing, they'll want to take an extra
13 dose to stop it.

14 They -- as I recall -- I can't recall with
15 clarity, but ordinarily we would like to put a dose or
16 two the first day or two at most, perhaps even a one
17 shot deal from how the note goes down lower, which would
18 not necessarily imply a chronic doubling of the dose for
19 extended periods of time.

20 Q Well, he felt -- under Chief Complaint it says,
21 "He felt terrible on the first. Hands tingling and
22 going numb. Heart doing flip-flops, light-headed, neck
23 and chest pains."

24 You see that; correct?

25 A Correct.

1 Q Would it be fair for me to conclude that you,
2 as a cardiologist, in looking at this and nothing else,
3 would think he was having --

4 MR. ERNST: Let's go off the record.

5 (Interruption in the proceedings.)

6 (Record read.)

7 MR. MORIARTY: -- some episode of atrial
8 fibrillation?

9 THE WITNESS: That's correct.

10 BY MR. MORIARTY:

11 Q Okay.

12 A But he was notoriously inaccurate about
13 feeling -- I shouldn't say "notorious." He was -- many
14 times he would not think that he was in fibrillation and
15 thought he wasn't, and vice versa, and his symptoms
16 didn't correlate real well all of the time.

17 Q Okay. But at least, according to what you
18 believe, he would have taken, when it says he doubled up
19 on his Lanoxin, instead of taking .50 per day, he was
20 taking one --

21 A One milligram.

22 Q -- milligram per day?

23 A At least on one day, if not several.

24 Q Do you know how many days --

25 A I'm sorry, I don't.

1 Q -- he did that?

2 And I don't see anywhere in here that you
3 diagnosed him as having digoxin toxicity; is that
4 correct?

5 A That's correct.

6 Q Did you even run a digoxin concentration level?

7 A No. I have to check the record, but I don't
8 know that I did. Certainly, if he had remained on it
9 for an extended period of time I would have. But a one-
10 or two-shot deal we would not have done that.

11 Q When you say "a one- or two-shot deal," if a
12 patient were to either intentionally or inadvertently
13 take a double dose for a day or two, that ordinarily
14 would not lead to digoxin toxicity; is that correct?

15 MR. ERNST: Objection.

16 BY MR. MORIARTY:

17 Q Correct?

18 A That would be correct. Again, it depends on
19 the patient.

20 We have some elderly people have a lower GFR.
21 You have a younger person such as him who had a
22 relatively stable level and normal GFR, we would not
23 ordinarily run a level.

24 Q In looking at every medical record I had
25 available to me I didn't see a single GFR lab result.

1 Do you know if there were any on Mr. McCornack in the
2 last five years of his life?

3 A Not that I know of, no. Ordinarily, the GFR is
4 calculated from the BUN and creatinine and albumin, so
5 the BUN and creatinine are pretty good markers as far as
6 GFR is going to be. It would be unusual to do one.

7 Q It would be hard to do a calculation now, just
8 based on his BUN and creatinines that are in the charts
9 because you wouldn't really know if he was in volume or
10 not; correct?

11 A That's correct, yeah. But it's supply,
12 production, removal process. If you produce more, it's
13 going to be a little bit higher. But if it's removed
14 rapidly...

15 Q Are there patients who can have consistently
16 and safely taken a digoxin dose who suddenly become
17 toxic even if they are on the same dose?

18 A It's possible, yes.

19 Q Okay. Or, instead of using the word "toxic,"
20 people could have taken the same dose consistently and
21 safely, and had an elevated level for some reason?

22 A Yes.

23 Q Have you ever seen any serum digoxin
24 concentrations for Mr. McCornack, while he was alive,
25 that were elevated?

1 A Not to my recollection.

2 Q Did you ever see any medical records to
3 indicate while he was alive that he had digoxin
4 toxicity?

5 A No.

6 Q If a patient consistently took a double dose,
7 for example, would you expect at some point that they
8 would demonstrate signs or symptoms of toxicity?

9 MR. ERNST: Objection. Go ahead and answer the
10 question.

11 THE WITNESS: Sometimes, yes. Sometimes, no.

12 BY MR. MORIARTY:

13 Q All right. Mr. McCornack consistently had
14 elevated uric acid levels. Are you aware of that?

15 A I didn't recall, but usually that's what
16 Allopurinol is used for.

17 Q If Dr. Lemm attributed his elevated uric acid
18 levels to gout, would you have any reason to disagree
19 with him?

20 A Well, a gout is a symptom of elevated uric acid
21 given the clinical signs. But, yeah, they go hand in
22 hand.

23 Q What's the cause of the elevated uric acid
24 level?

25 A It happens.

1 Q Mr. McCornack consistently had elevated SGPT
2 levels. Were you aware of that?

3 A Yes.

4 Q Did you have any opinion to a probability as to
5 the cause of that?

6 A Don't know. It could be a hepatitis.
7 Sometimes people that -- although he was not obese, as
8 best I can tell, some people will have a fatty liver. I
9 don't know the cause of that.

10 Q And several times I've said, "Do you have an
11 opinion to a reasonable degree of medical probability?"
12 What is your understanding of "reasonable degree of
13 medical probability" in expressing an opinion in this
14 setting?

15 MR. ERNST: Objection.

16 THE WITNESS: I'm sorry, I don't quite
17 understand.

18 BY MR. MORIARTY:

19 Q Well, I don't want you to guess or speculate.
20 When I ask, do you have an opinion to a
21 reasonable degree of medical probability, do you
22 understand that I mean a certain level of scientific
23 accuracy?

24 MR. ERNST: Objection.

25 \\\

1 BY MR. MORIARTY:

2 Q Go ahead.

3 A I guess I would question whether an alternative
4 way of saying that, if you had a list of ten choices,
5 and choice number one would be -- happen over 50 percent
6 of the time, I would say that would be the most probable
7 and most likely.

8 Q Okay.

9 A Does that make any sense?

10 Q Sure. So you're equating likely with more
11 likely than not or greater than 50 percent?

12 A All things considered, I would think so.

13 Q Okay. And in order to form opinions about
14 particular subjects, do you think it's important that it
15 be something within your subspecialty and that you have
16 the basic reliable data to express an opinion?

17 A Hopefully.

18 Q All right. So, if I asked you a string of
19 opinion questions about orthopedic issues, you might
20 decline because it's not your specialty; fair?

21 A Unless I happen to have some independent
22 knowledge in a particular area.

23 Q Sure. Mr. McCornack had elevated BUNs on nine
24 occasions between June of 2001 and May of 2007. Do you
25 have any opinion to a reasonable degree of medical

1 probability as to the cause of that?

2 A My best would be the fact that that's a normal
3 variance among the population. Get young, healthy,
4 muscular guys, their BUNs and creatinines tend to run a
5 little bit higher just because of the muscle mass.

6 Q Are you aware of any serum digoxin
7 concentration draws after May 15, 2007?

8 A I don't have my records here, but no, I'm not
9 aware of any.

10 Q Have you ever done any research about
11 postmortem redistribution of digoxin?

12 A No.

13 Q Have you ever done scientific lab studies about
14 postmortem redistribution of any drug product?

15 A No.

16 Q And I guess my first question wasn't very
17 clear. When I say, have you done any research about it,
18 I meant in reading the medical literature.

19 A Not until looking at the Goodman and Gilman or
20 PDR.

21 Q In your career as a cardiologist, how many
22 times do you believe that you have looked at and
23 analyzed postmortem blood levels?

24 A I'm sorry. Very, very rarely. Almost never.

25 Q All right. Have you ever, to your memory,

1 encountered postmortem diltiazem levels before?

2 A No.

3 Q Before looking at Exhibit 2 in the last few
4 days, how many times in your career do you think you've
5 encountered postmortem digoxin levels?

6 A Probably less than half a dozen.

7 Q What were those circumstances in those other
8 instances where you did encounter postmortem digoxin
9 levels?

10 A Ordinary -- well, there would be someone who
11 died unexpectedly, and they're very ill, we didn't know
12 why they had died, and we might ask the pathologist to
13 go back and draw all sorts of levels to see what was
14 there.

15 Q Did you ever talk to the pathologist about the
16 meaning and significance about postmortem digoxin
17 levels?

18 A It's been so long ago, I don't recall.

19 Q Do you know anything about the degree to which
20 postmortem digoxin levels are reliable indicators of
21 antemortem levels?

22 A Other than the article Dr. Ernst ran by me, I
23 don't.

24 Q Dr. Ernst?

25 MR. ERNST: I am a doctor.

1 MR. MORIARTY: You've been promoted.

2 MR. ERNST: I am a doctor.

3 MR. MORIARTY: If he gets the promotion, I get
4 the promotion.

5 MR. ERNST: You can have the promotion. And
6 Alicia, too.

7 BY MR. MORIARTY:

8 Q Is it your understanding, in general, that
9 concentrations postmortem do not necessarily reflect
10 those at the time of death?

11 A I couldn't answer, because some things can vary
12 tremendously and some I would expect wouldn't vary much.

13 Q Do you have any information about when
14 Dan McCornack took his last digoxin dose before he died?

15 A No.

16 Q And I assume that you haven't seen any EKGs or
17 serum digoxin concentrations that were taken unbeknownst
18 to me in the last 24 hours before he died?

19 A That's correct.

20 Q Has anybody explained to you or have you read
21 anything to indicate that he had clinical signs or
22 symptoms of digoxin toxicity the day before he died?

23 MR. ERNST: Objection. Go ahead answer the
24 question.

25 THE WITNESS: The only thing -- the only way I

1 could answer maybe what was put in the deputy's report
2 per the response to the family's call to distress.

3 BY MR. MORIARTY:

4 Q There was nothing in there to lead you to
5 think, clinically, that he had digoxin toxicity?

6 A Sounded like a usual day.

7 Q Would it be fair to say that he had sudden
8 death?

9 A Sounds very likely.

10 Q Let's start there.

11 MR. ERNST: Objection.

12 BY MR. MORIARTY:

13 Q Let's start there.

14 A Sounds very likely.

15 Q Is it likely that he had sudden cardiac death?

16 MR. ERNST: Objection. You can go ahead and
17 answer the question.

18 THE WITNESS: Most likely, yes.

19 BY MR. MORIARTY:

20 Q Okay.

21 A In the pathologist's report a lot of other
22 things didn't happen, like G.I. bleeding and pulmonary
23 embolis.

24 Q Sure. Do you know anything about the
25 reliability of postmortem blood sampling as it relates

1 to the time that the sample is drawn from the corpse
2 after death?

3 A No.

4 Q So, to put it another way, you don't know
5 whether a specimen drawn at two hours is more or less
6 reliable than a specimen drawn at 72 hours?

7 A That's correct.

8 Q Have you ever seen any evidence that
9 Dan McCornack took a digoxin tablet that had a dose of
10 digoxin in excess of the labeled amount?

11 A I'm unaware of that.

12 Q In the summer of 2007, did you refer
13 Dan McCornack to Dr. Winkle at Stanford?

14 A If that was the date of this consultation, yes.
15 I'm not sure of the years.

16 Q Okay. Why Dr. Winkle at Stanford?

17 A In the treatment of atrial fibrillation --
18 well, numerous nonmedical attempts have been tried or
19 developed to stop or treat atrial fibrillation, and
20 Dr. Winkle has expertise in that field of
21 electrophysiology where with a catheter procedure they
22 can sometimes damage the parts that are causing the
23 fibrillation and restore normal rhythm.

24 Q Well, I guess my question is, are there people
25 in San Luis Obispo or Paso Robles, or even San Jose who

1 have expertise in radiofrequency ablation?

2 A Not in our county. But there are other
3 communities, other parts of the state.

4 Q Okay.

5 A I just happen to know Dr. Winkle for a long
6 time, and he's been a very solid guy who is sort of
7 leading the field in many ways.

8 Q Okay. And from your understanding of
9 Dr. Winkle's consult note, did he recommend that Dan
10 have radiofrequency ablation?

11 A I would have to check the terminology, but I
12 believe he advised him that he would be someone who may
13 benefit from the procedure.

14 Q When you saw Dan at subsequent visits, did you
15 echo Dr. Winkle's sentiment that Dan may be one of those
16 people who could benefit from the procedure?

17 A Yes.

18 Q And if Dan had had the procedure, would that
19 most likely have reduced his reliance on the combination
20 of diltiazem and digoxin to control his heart?

21 MR. ERNST: Objection.

22 THE WITNESS: That would be the intent of the
23 procedure.

24 BY MR. MORIARTY:

25 Q Does RFA typically eliminate the need for those

1 drugs all together?

2 A Um, in the majority of cases, yes. Not always.

3 Q Did you ever have any discussions with
4 Dan McCornack in the summer or fall of 2007 about
5 whether he was going to have that procedure?

6 A I don't recall. We had -- we were going to set
7 him up -- you have notes there. Make another attempt at
8 cardioversion. But, ordinarily, once you've been in
9 fibrillation as long as he had, it would not be likely
10 to be a long-term success.

11 Q What would not likely --

12 A The cardioversion shock and rhythm
13 defibrillation back to sinus rhythm.

14 Q Why was that going to even be tried?

15 A I can't recall. Most likely, it would have
16 been him wanting to make sure we had tried all
17 possibilities before going on to a procedure, but I can
18 only guess.

19 Q Well, we know ultimately that Dan did not have
20 radiofrequency ablation. Do you have any memory, from
21 talking to him or his wife, Kathy, about why he did not
22 have it?

23 A No.

24 Q There is a comment in your notes in November of
25 2007 that, at least up to that point, he had delayed the

1 procedure because it was hunting season?

2 A Yep. Yes. I'm sorry, you want yep, yep, nope.

3 Q There are a number of notations. I'm not sure
4 I counted them all. But at least six notations in all
5 of the medical records between June of 2001 and your
6 office visit of November 29th, 2007, where Dan McCornack
7 complains of persistent fatigue. Okay. Is that likely
8 related to his atrial fibrillation?

9 A That and the fact that the guy's over 40.

10 Q And weighs 225 pounds?

11 A Yep.

12 Q But the -- is atrial fibrillation a disease --
13 in a man like Dan McCornack, can it cause fatigue for
14 one reason or another?

15 A Commonly.

16 Q Okay.

17 A It's usually most noticeable at higher levels
18 of exertion. When people are doing day-to-day
19 activities, oftentimes it's not as noticeable.

20 He was very active, and he would want to go
21 over hill over dale in ways he did when he was younger,
22 he would notice he couldn't do as well as he did
23 previously.

24 Q I think in the notes there are times when he
25 complains he can't keep up with his father on the golf

1 course. Do you remember those notes?

2 A Something like that.

3 Q So when you're comparing your condition with
4 somebody who is at least presumably 18 or more years
5 older than you are, that's some sign of a problem other
6 than just deconditioning; correct?

7 A Common.

8 Dr. Winkle is usually very good at presenting a
9 very evenhanded approach to the likelihood of his
10 success.

11 As I recall, he did not offer them 100 percent
12 chance of success, and some people, depends if your cup
13 is half full or half empty.

14 The fact is that Dr. Winkle will not try to
15 sell you a product without you knowing exactly what your
16 odds of success and failure are.

17 Q It's one of those risk benefit analyses?

18 A Exactly.

19 Q Okay. In general, did Mr. McCornack's atrial
20 fibrillation get worse over time?

21 A Either you're in it or you're out of it. And
22 once he had it, it pretty much was unchanged.

23 Q I'm just looking at it from originally he was
24 on no digoxin. Then he was on .25 a day. Then .5 a
25 day.

1 By May of 2001 there were plans for holter
2 monitoring.

3 By July of 2001, he was increasing his
4 diltiazem.

5 And then by 2007, Dr. Winkle is at least
6 advising of the possibility of ablation being
7 beneficial.

8 Is that a progression that demonstrates a
9 worsening?

10 A I wouldn't say that. I mean, in some ways
11 it's -- the fact that Dr. Winkle -- well, again, if you
12 had asked to have an ablation ten years ago, I would say
13 the odds to success are very low.

14 Over the last five years, not only Dr. Winkle,
15 but other people have done better and more effective and
16 more safety. This would be in the time zone when the
17 process was being developed with greater safety and
18 greater efficacy.

19 Also as Mr. McCornack was symptomatic and
20 shortness of breath, tiredness, fatigue, can sometimes
21 be subtle and not always appreciated that the heart is
22 going faster than what it really should, and if you can
23 slow that down, in particular at times of exercise,
24 people will sometimes do better. Hence, he got the
25 higher dose of medication. And diltiazem in particular

1 is noted to be helpful to keep the heart from racing
2 really fast when you get to be more physically active.
3 So I would call it more fine tuning of treatment as far
4 as the medications. And then increasing -- well,
5 progress being made in the field of radiofrequency
6 ablation.

7 Q Okay.

8 A I think Dr. Winkle's numbers are significant --
9 I shouldn't say -- they are certainly better now as he
10 offers the procedure because they've become smarter
11 about how to do the procedure.

12 Q Sure. Who's Jesse Malone?

13 A She's a nurse practitioner who works in our
14 office.

15 Q Mr. McCornack was in your office on
16 November 29th, 2007. Did he see anyone other than
17 Jesse Malone and possibly a medical assistant?

18 A Likely not. She and I have desks right next to
19 each other, and we are usually in pretty frequent
20 communication about things.

21 Q Okay.

22 A She --

23 Q Go ahead.

24 A She's an intensive care unit nurse at Stanford
25 University, with a particular strength in heart, and

1 she's been a very valuable asset to our practice.

2 Q Is that the last office visit indicated in your
3 Coastal Cardiology notes?

4 A That I have here. I'd have to look in the
5 computer to be sure.

6 Q Have you been asked by Mr. Ernst or anybody
7 else to express opinions about the cause of
8 Mr. McCornack's death as part of this litigation?

9 A Mr. Ernst asked me.

10 Q Okay. He asked. Are you intending to give
11 opinions to a reasonable medical probability about the
12 cause of his death?

13 A No. I can.

14 Q I'm sorry?

15 A I can.

16 Q Well, I don't want to ask if you don't intend
17 to give them, or if he doesn't intend to elicit them
18 from you.

19 MR. ERNST: I didn't hear the last answer.

20 (Record read.)

21 MR. MORIARTY: Are you going to elicit opinions
22 from this witness about the cause of Mr. McCornack's
23 death?

24 MR. ERNST: Well, when you're done questioning.
25 I haven't asked questions. Depends on what you take --

1 what comes out in this deposition.

2 MR. MORIARTY: Well, I think I'm entitled to
3 know, because if I stop and you don't ask him any, I
4 don't want to have to come back to California four
5 months from now and ask him opinion questions.

6 MR. ERNST: Why don't you ask him? I'm going
7 to have a series of questions. If you don't, I will,
8 let me put it that way.

9 BY MR. MORIARTY:

10 Q Is there such a thing as postmortem chemistry
11 panels?

12 A I mean, you can draw a blood specimen anytime
13 that you want, but not ordinarily.

14 Q Okay. Well, we know there was a postmortem
15 blood sample drawn over 70 hours after Mr. McCornack's
16 death; correct?

17 A I'd have to check the timing, but, yes.

18 Q But we don't have BUNs, or creatinines, or
19 potassiums, or calciums run as part of that analysis?

20 A Okay.

21 Q Correct?

22 A As far as I know.

23 Q So we don't have any -- anything that would
24 reflect what his electrolytes were within five minutes
25 from when he died; right?

1 A That's correct.

2 Again, some of those I think may vary more than
3 others, and I'm not -- I don't know how. Certainly
4 potassiums can vary tremendously.

5 I don't know how the BUN and creatinine would
6 vary over a period of time after. But just with the
7 acidotic process of death, potassium levels go very
8 high. They will not be meaningful of the things that
9 were going on until the moment of whatever event. I
10 couldn't tell you the individual variation unless you're
11 saying postmortem redistribution.

12 Q We talked earlier about potassium levels could
13 potentially precipitate arrhythmias?

14 A Yes.

15 Q We don't have any evidence either way about
16 whether a high potassium precipitated Mr. McCornack's
17 arrhythmia assuming he had one?

18 A You wouldn't know unless you drew one just
19 before the arrhythmia happened.

20 Q But we don't have that evidence here; correct?

21 A That's correct.

22 Q We don't have an electrocardiogram that
23 indicates what his rhythm was doing up until the moment
24 he died; right?

25 A I wish we had one, but, no.

1 Q We don't have one?

2 A We don't.

3 Q And I think I asked this before, but we don't
4 have a -- there's been no report to you of clinical
5 signs or symptoms of digoxin toxicity that day or night;
6 correct?

7 A That's correct.

8 MR. ERNST: Objection. Asked and answered.

9 BY MR. MORIARTY:

10 Q Are you aware that Mr. Ernst had five or six of
11 Mr. McCornack's Digitek tablets tested for potency by
12 NMS Laboratories?

13 A He mentioned that, yes.

14 Q Did he tell you what the results were?

15 A I believe he said they were within normal
16 limits.

17 Q Did you know that Dr. Mason, the coroner in
18 Santa Cruz County, changed the autopsy in the death
19 certificate after Mr. Ernst retained him as an expert in
20 this case?

21 MR. ERNST: Objection.

22 THE WITNESS: I was unaware of that. I would
23 have presumed he may have changed it after he first saw
24 the lab results.

25 \\\

1 BY MR. MORIARTY:

2 Q What are the -- what's the date of that lab
3 result in Exhibit 2? It's up at the top.

4 A June 24th.

5 Q 2008; right?

6 A Right.

7 Q That's been around for a year and a quarter;
8 correct?

9 A Yes.

10 Q Have you ever heard of a coroner changing an
11 autopsy or death certificate after a year and a quarter?

12 MR. ERNST: Objection.

13 THE WITNESS: I'm not privy to how often that
14 does happen or whatever. I -- well, I can only make
15 presumptions, but I don't know.

16 BY MR. MORIARTY:

17 Q Does it strike you as a little unusual that the
18 coroner would change the autopsy and the death
19 certificate a year and a quarter after Mr. McCornack
20 died?

21 MR. ERNST: Objection.

22 BY MR. MORIARTY:

23 Q Go ahead.

24 A I could only speculate that he was unaware of
25 the result until that time. We get so much lab through

1 our office, and sometimes we see it and sometimes we
2 don't.

3 Q This result is actually addressed to the
4 coroner's office, isn't it?

5 A It might well be.

6 Q Right there.

7 A Again, I can only speculate. I have no
8 knowledge.

9 Q I don't want you to guess.

10 MR. ERNST: Well --

11 BY MR. MORIARTY:

12 Q I've got enough people guessing in lawsuits.

13 I'm asking you, if you don't know the answer to
14 my question, you are more than welcome to tell me you
15 don't.

16 A I don't know why or when this data became
17 available.

18 Q I want you to assume that that was received at
19 the coroner's office shortly after it was published in
20 June of 2008 and that they had it in their files for a
21 year and a quarter before Dr. Mason changed his reports.
22 Do you think that's a little unusual?

23 MR. ERNST: Objection. Calls for speculation.

24 BY MR. MORIARTY:

25 Q Well, whether you think it's unusual is not

1 speculative at all.

2 A In an ideal world, he would have seen it and
3 put it all together at the time, and not had reason to
4 change at this date.

5 Q Does that mean it's a little unusual?

6 MR. ERNST: Objection. Argumentative.

7 THE WITNESS: I would think so.

8 BY MR. MORIARTY:

9 Q All right. Before today, in fact, have you
10 ever written anything in your medical records or a
11 letter to Mrs. McCornack, or even a letter to Mr. Ernst,
12 expressing an opinion on Dan McCornack's cause of death?

13 A No.

14 Q Do you know anything about what the forensic
15 toxicologist at NMS Labs said about the reliability of
16 this postmortem digoxin level of 3.6 --

17 A No.

18 Q -- in predicting levels prior to death?

19 A I do not.

20 Q Do you have an opinion to a reasonable degree
21 of medical probability as to Dan McCornack's cause of
22 death, direct cause of death? In other words, did he
23 have an M.I.? Did he have an arrhythmia, or something
24 else?

25 A You're asking me to give that opinion?

1 Q Yes. Do you have such an opinion?

2 A Um --

3 Q If your answer is, no, you don't have one to a
4 probability, that's fine.

5 A Well, if you were twisting my arm and forcing
6 me to choose why did this man die, it would be very -- I
7 think most likely that he would have had digitalis
8 intoxication with an arrhythmia death.

9 You take 10,000 people with these
10 circumstances, that would be my best guess, because the
11 pathologist didn't talk about intracranial bleeding,
12 didn't talk about G.I. bleeding. M.I.s can be not
13 always picked up at autopsy.

14 You've mentioned all of the pitfalls
15 potentially of him taking digitalis dose a couple hours
16 before he died, or for all we know he could have skipped
17 doses. There's so much to speculate about that.

18 Using the big crayons, for a guy not having an
19 obvious cause of death, with an elevated digitalis level
20 realizing there can be some postmortem redistribution to
21 some extent, I guess out of 10,000 cases, my opinion
22 would be half the time that would turn out to be the
23 outcome.

24 Q What's the basis for your opinion?

25 A All of the things that we've mentioned. The

1 fact that he was on digitalis. The fact that it was
2 elevated. The fact that he didn't have a number of
3 other things that can commonly put down a young guy like
4 that. But I could easily be wrong.

5 Q But if digoxin precipitated an arrhythmia, you
6 need to know what the level was at the time that
7 happened; correct?

8 A Right.

9 Q And you told me earlier that you have no basis
10 to know the meaning of the postmortem 3.6 nanograms per
11 milliliter in predicting predeath levels; correct?

12 MR. ERNST: Objection.

13 THE WITNESS: Yeah. The things I would like to
14 know to be firm in that opinion, if you will, would be
15 the science behind the laboratory which you're talking
16 about, to know whether it rises 2 percent after death or
17 20 percent. All of the things that you mentioned
18 occurs.

19 It could be that everybody has a distribution
20 much higher, but then the number of hours after the
21 death at the time the sample was drawn.

22 Again, I don't know what time he took a pill
23 ahead of time. If he dutifully took his medication at
24 the time of day before he went to bed and he had taken a
25 dose or even an overdose, that could certainly explain

1 it as well.

2 BY MR. MORIARTY:

3 Q Okay.

4 A For all I know, he skipped the dose and could
5 have had high levels forever and forever.

6 Your company may know what pills he actually
7 received and how much was in the medication.

8 Q You're not expressing any opinion as to the
9 cause of an elevated level in this case, are you?

10 A No.

11 Q And I think when you were explaining this, when
12 you used the term "big crayons," you said this was your
13 best guess; right?

14 A That would be a very simple-minded basic fact.
15 Not trying to speculate too much on the situation at
16 hand.

17 MR. MORIARTY: Let's take a break. We haven't
18 taken one at all. Let's spend five minutes. Then we'll
19 come back and see where we stand.

20 (Recess.)

21 BY MR. MORIARTY:

22 Q Do you keep a research folder on postmortem
23 redistribution?

24 A No.

25 Q Do you keep a research folder on digoxin topics

1 in general?

2 A No.

3 Q Given the fact that Mr. McCornack's postmortem
4 diltiazem level was 630, isn't it likely that diltiazem
5 was a substantial contributing factor to causing an
6 arrhythmia which caused his death?

7 A Um, again, with our previous conversation, I
8 don't know again the postmortem distribution of
9 diltiazem. I don't know the therapeutic index, if you
10 will, of diltiazem.

11 By the report, when they went to measure a
12 certain therapeutic effect, they will give it certain
13 values. But I'm unaware of other circumstances that may
14 be useful. And we so have commonly given diltiazem in
15 this dose and not observed clinical toxicity, and he's
16 been on it for so long, I would not expect -- I'd love
17 to have more information but what's been presented so
18 far I couldn't be worried about that a lot.

19 Q You commonly gave, at least Mr. McCornack, .25
20 two times a day; correct?

21 A Of the digoxin.

22 Q He'd been on it a long time; correct?

23 A That's correct.

24 Q And it had never caused him problems; correct?

25 A That's correct.

1 Q And diltiazem does elevate serum digoxin
2 concentrations, does it not?

3 A Which is why we usually will carefully check
4 the level a number of times with any fixed combination
5 of the medication.

6 Q But to some degree, diltiazem could have
7 elevated that level, correct, the level in the
8 Exhibit 2?

9 A I suspect that if we had stopped his diltiazem
10 his serum digoxin level would have run lower than it
11 what had been measured in the past when he was on
12 diltiazem.

13 Q Well, you have no reason to believe that
14 diltiazem in his blood specimen wasn't acting in some
15 manner to elevate the digoxin level, do you?

16 A Because diltiazem affects the renal clearance
17 of the digoxin --

18 Q Sure.

19 A -- I would expect it to have been exerting some
20 effect all along in a standard manner, predictable
21 manner.

22 Q Quinine is known to increase serum digoxin
23 concentrations, is it not?

24 A I'd have to look that up.

25 Q I think in your answer to me earlier about

1 diltiazem, you said you don't know if the -- you know
2 what the therapeutic -- I'm sorry, you don't know what
3 the therapeutic levels are in living patients for
4 diltiazem; correct?

5 A That's correct. And different laboratories may
6 report different values.

7 Q Then for digoxin, the .8 to .2 is the common
8 level for living patients; correct?

9 A That's correct.

10 Q And you can't quantify the degree to which
11 digoxin may have redistributed in the 70 plus hours from
12 the tissues into the blood before this blood sample was
13 drawn; correct?

14 A That's correct.

15 MR. MORIARTY: All right. I don't have any
16 other questions.

17 THE WITNESS: I know then that, in general, it
18 may rise some. As far as I know, it's not huge. But
19 I'm not an authority on that topic.

20

21 EXAMINATION

22

23 BY MS. DONAHUE:

24 Q Dr. Von Dollen, I have a few questions. We met
25 off the record. My name is Alicia Donahue. I represent

1 the Mylan defendants in this case.

2 A And --

3 Q Those are the distributing defendants.

4 MR. MORIARTY: I represent manufacturing
5 defendants called Actavis.

6 THE WITNESS: Okay.

7 MR. MORIARTY: She represents a distributor
8 called Mylan.

9 BY MS. DONAHUE:

10 Q I have a couple of questions in regards to
11 specific notes in your file.

12 Mr. Moriarty asked you about the 11-29-07 note
13 which appears to be the last time that Mr. McCornack was
14 in your office; is that correct?

15 A Okay.

16 Q And I think you told us that, on that date, he
17 saw --

18 A Jesse Malone.

19 Q Did he also see the medical assistant
20 Sakisha Alexander?

21 A Yes.

22 Q And in that record there's a reference to
23 Mr. McCornack having a number of different medications
24 that he took regularly, and one is aspirin; is that
25 correct?

1 A That's correct.

2 Q Was that a prescription level of aspirin or a
3 regular over-the-counter aspirin?

4 A 325 is over-the-counter.

5 Q And he had been taking that, it looks like, for
6 at least the past year, because there's also a reference
7 to it in the 11-27-06 note --

8 A Yes.

9 Q -- is that right?
10 Do you know if he'd been taking it regularly
11 longer than that?

12 A He just took at the notes. You said 2006?

13 Q Yeah.

14 A I don't know.

15 Q Okay. Was he taking that -- the aspirin at
16 your direction?

17 A Yes.

18 Q Was it for anticoagulant purposes?

19 A It's a very mild anticoagulant. Most people
20 who don't take Coumadin are advised to take aspirin.

21 Q Okay. As far as you were concerned, if
22 Mr. McCornack had chosen to go with the ablation
23 procedure that he consulted with Dr. Winkle for --

24 A Uh-huh.

25 Q -- would he have -- would it have been

1 necessary for him to go to take another form of an
2 anticoagulant other than aspirin?

3 A If he had had the procedure and if it were
4 successful, would he have required anti-coagulation?

5 Q Let's do it two ways. In order to have the
6 procedure, prior to the procedure would he have needed
7 to go on a different anticoagulant other than the
8 aspirin?

9 A Dr. Winkle could probably better answer that.
10 Ordinarily not, I don't think so.

11 Q Okay. And what about post procedure, as far as
12 you know?

13 A That has varied. Sometimes they'll have had
14 them on anti coagulation for a period of weeks or months
15 afterwards, but certainly not long term.

16 Q Thank you. Under the -- going back to the
17 11-29-07 note, under Plan, I take it that the three
18 items referenced in the plan were items that were
19 discussed with him by Jesse Malone?

20 A Right.

21 Q And it says that "Mr. McCornack is very unclear
22 about what he would like to do at this time in regard to
23 treatment options"; correct?

24 A Correct.

25 Q It indicates after Number 2 that, Ms. Malone

1 will discuss with you and get your thoughts on
2 Mr. McCornack's treatment options?

3 A Right.

4 Q Is there any notation in your record that
5 Ms. Malone had that discussion with you?

6 A No. Well, I remember us talking in the office.
7 And I'd have to go back to Dr. Winkle's note to give you
8 the details because I recall they gave him a two-thirds
9 chance of having this procedure be successful round one.

10 And Mr. McCornack was very happy not to be
11 bothered by medicines or procedures or anything like
12 that. And I suspect -- I can speculate, if you will,
13 that he was weighing the odds, "If I go through this
14 whole thing and it doesn't help me a third of the time,
15 do I still want to go through it or not?"

16 But we'd gone through a lot of these
17 discussions together and he was pretty well-informed.
18 So, when he wanted to commit, he would commit. When he
19 didn't, he didn't.

20 Q There's no -- you don't have any indication
21 that he committed to any treatment options?

22 A No, he was in direct contact with Dr. Winkle
23 and should he have wanted the procedure he could have
24 called up any time and set it up.

25 Q He didn't indicate to anyone in your office

1 that he decided to change his treatment option after --

2 A No.

3 Q -- 11-29-07?

4 A He did want to go hunting.

5 Q Pardon me?

6 A He did want to go hunting.

7 Once we refer to Dr. Winkle, we kind of we're
8 there, but at the same time we don't put ourselves in
9 between them and the physician.

10 Q Well, someone -- Ms. Malone in your office was
11 discussing treatment options --

12 A Yes.

13 Q -- with the patient; correct?

14 A Yes. And we were all saying the same thing.

15 Q It was his decision?

16 A Yes.

17 MS. DONAHUE: Okay. Thank you. That's all I
18 have.

19

20 EXAMINATION

21

22 BY MR. ERNST:

23 Q With regard to this radiofrequency ablation,
24 there wasn't a critical time issue, was there?

25 A No. I mean, it could have been today, last

1 week, next week.

2 Q So it wasn't an immediate time that it needed
3 to be done now or a particular time?

4 A That's correct.

5 Q Coumadin was part of the treatment regimen of
6 that?

7 A Dr. Winkle will sometimes have people be on
8 anti coagulation ahead of time. Because his heart
9 structures were pretty normal, a lot of times they
10 won't.

11 They are concerned that once they start
12 tampering with the catheters they can knock clots loose
13 that are there. Certainly if someone has a large
14 atrium, then fibrillation a long time has more
15 structural heart disease they will want to be on
16 anticoagulants before the procedure. Someone such as
17 him, as I recall, they were as common as walk in off the
18 street and have the procedure.

19 Q He didn't have a lot of what you call
20 structure?

21 A Structural heart chambers. He may have had
22 mild thickening of the heart muscles, but certainly the
23 chambers were normal size, valves worked fine.

24 Q Doctor, I have a series of questions I want to
25 ask you about your knowledge.

1 You've treated Mr. McCornack for a great number
2 of years. I think 12, 13, 14 years, something like
3 that; is that accurate?

4 A Yes. I have to check the dates. Somewhere
5 about.

6 Q To your knowledge, did Dan McCornack ever have
7 impaired renal function?

8 A No.

9 Q And to your knowledge, was Dan McCornack
10 compliant with his medication regimen?

11 A To the best of my knowledge. I wasn't really
12 close to him in that regard, but the levels were
13 certainly consistent. By the family's report, he had
14 taken it. He did tell me when he deviated the dose.

15 Q You treated and cared for Dan McCornack; true?

16 A Yes.

17 Q Was his death a surprise to you?

18 A Yeah.

19 Q Were you aware that there had been a recall for
20 Digitek?

21 A Yes.

22 Q When you look at the facts that you have with
23 regard to the training, experience, your hands-on
24 clinical examination and knowledge of Mr. McCornack over
25 a period of over ten years, is his death consistent with

1 digoxin toxicity?

2 MR. MORIARTY: Objection.

3 THE WITNESS: Yeah. Certainly, if he had had
4 digitalis toxicity, he could have died in this manner.

5 BY MR. ERNST:

6 Q Now, earlier you gave an answer to one of
7 Mr. Moriarty's questions that involved the word best
8 guess, but I don't want your best guess. I want your
9 best estimate or your opinion, if you will, as you sit
10 here today.

11 As you sit here today, knowing that there was a
12 postmortem --

13 MR. MORIARTY: Sorry, I clipped those together.

14 BY MR. ERNST:

15 Q -- finding of digoxin level of 3.6 nanograms
16 per milliliter, together with the circumstances
17 surrounding his death, his age and his clinical history,
18 and the personal observations that you have made, what
19 do you think is the most likely cause of his death?

20 MR. MORIARTY: Objection.

21 MS. DONAHUE: Objection.

22 MR. MORIARTY: Form and otherwise.

23 MR. ERNST: You can go ahead and answer the
24 question.

25 THE WITNESS: Of all of the possibilities

1 presented, I would -- I would -- I would -- my opinion
2 would be digitalis intoxication would be the most common
3 cause, with all of the caveats we've mentioned.

4 BY MR. ERNST:

5 Q Now, as you sit here today, that is your pick?

6 A Right.

7 MS. DONAHUE: Objection.

8 BY MR. ERNST:

9 Q There's always more work that you can do. You
10 can do more research, more studies, do all sorts of
11 things, but as you sit here today, that's what you
12 think?

13 A That's correct.

14 MR. ERNST: Thank you. That's all I have.

15 MR. MORIARTY: I don't have anything else.

16 MS. DONAHUE: Me neither.

17 MR. MORIARTY: I think Dr. Von Dollen should
18 read and sign his transcript, which means you're going
19 to get this. You have a chance to read it, make sure
20 she took down a lot of these words right. There are
21 times when I talk fast, you talk fast. Just to make
22 sure that the transcript is accurate. Okay?

23 THE WITNESS: I'm not good at rereading things,
24 But, yeah.

25 MR. MORIARTY: And then there will be a

1 separate sheet, and if there's a mistake you note it on
2 the separate sheet. Keep the transcript for your own
3 file and you can send the sheet back to the court
4 reporter or --

5 MR. ERNST: I have a couple more questions. I
6 have a couple more thoughts.

7 MR. MORIARTY: No, we were done. The
8 deposition is over.

9 MR. ERNST: You don't want to allow me to ask
10 any more questions, Counsel?

11 MR. MORIARTY: I owe you a favor. Maybe.

12 Okay. Go ahead. Don't be surprised if it
13 spurs me to ask some. You may want to think twice.

14 MR. ERNST: Or three times. May I look at what
15 you've got here?

16 (Short pause in proceedings.)

17 MR. ERNST: I'm happy. Thank you.

18 Nothing further.

19 We're going to let you go quick.

20 You want to send the transcript to me?

21 Send it directly to him with a self-addressed,
22 stamped envelope.

23 MR. MORIARTY: Fine with me.

24 MS. DONAHUE: Yes.

25 MR. ERNST: Send the original to her.

1 And advise there will be a document in the
2 front you can make changes and corrections.

3 And do you usually send it back to the court
4 reporter? That's how you do it?

5 MS. DONAHUE: Yeah, the changes. Yes.

6 MR. ERNST: You'll receive it in the mail.

7 Make whatever changes you deem appropriate, but
8 you don't have to make any changes at all. If you want
9 to make changes, if you do, put them in the front and
10 send them back to the court reporter.

11 MS. DONAHUE: A letter will tell you there's a
12 30-day time period to do that. If you do nothing the
13 transcript stays the same.

14 MR. ERNST: You can sign under penalty of
15 perjury.

16 MR. MORIARTY: If you have questions about any
17 of that process, you can call Don or me. If you call
18 me, we're not going to talk about the case. We're just
19 going to talk about how to sign depositions.

20 And that's where you can reach me.

21 And if you are billing me for this two hours
22 and 25 minutes, that's where you bill me.

23 MR. ERNST: You didn't ask what the billing
24 rate is, but...

25 (Deposition concluded at 4:26 p.m.)

1 STATE OF CALIFORNIA)
) ss.
2 COUNTY OF SAN LUIS OBISPO)
3

4 WITNESS'S CERTIFICATE
5

6 I, Lawrence Von Dollen, M.D., declare that the
7 answers to the foregoing deposition are true to the best
8 of my knowledge and belief.
9

10 Dated this day of , 2009.
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Lawrence Von Dollen, M.D.
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1 STATE OF CALIFORNIA)
) ss.
2 COUNTY OF SAN LUIS OBISPO)

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4 REPORTER'S CERTIFICATE

5
6 I, Cindy D. Griffith, a Certified Shorthand
7 Reporter in and for the State of California, do hereby
8 certify:

9 That, prior to being examined, the witness
10 named in the foregoing proceeding was by me sworn to
11 tell the truth, the whole truth and nothing but the
12 truth.

13 That said deposition was taken before me at the
14 time and place therein set forth and was taken down by
15 me in shorthand and thereafter reduced to computerized
16 transcription.

17 I hereby certify that the foregoing deposition
18 is a full, true and correct transcript of my shorthand
19 notes so taken.

20 Dated at San Luis Obispo, California, this 14th
21 day of October, 2009.

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24 CINDY D. GRIFFITH
CERTIFIED SHORTHAND REPORTER

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16
17
18
19
20
21
22
23
24
25

A			
ability 48:7	agents 36:21 56:2	antihypertensive 25:14	assume 12:19 13:17 21:9
ablation 70:1,10 71:20	ago 5:2,6,14,24 8:4 9:22	26:1 47:20 56:2	24:10 67:16 81:18
74:6,12 75:6 90:22	49:19,20 55:6 66:18	antihypertensives 25:21	assuming 78:17
93:23	74:12	antiinflammatory 36:21	atrial 13:13 14:6 21:24
able 48:10	ahead 10:5 32:11 62:9	anti-coagulation 91:4	25:10 27:18,19,24 28:1
abnormal 34:13 38:23	64:2 67:23 68:16 75:23	anybody 67:20 76:6	29:21 42:16 43:4,7,13
abnormalities 36:17	80:23 84:23 94:8 96:23	anytime 77:12	43:20 46:10,14,17,18
absolutely 20:25	98:12	appear 7:22	46:18,24 47:25 48:7,13
accept 50:24	al 1:13	APPEARANCES 2:9	53:2,5,8 57:10 59:7
acceptable 51:17,21	albumin 61:4	appears 89:13	69:17,19 72:8,12 73:19
ACCFAHA 46:9	Alexander 89:20	applied 23:15	atrium 44:2 94:14
accuracy 63:23	Alicia 2:24 67:6 88:25	appointments 9:18	attempt 71:7
accurate 13:24 14:3 95:3	alive 31:22 51:7 61:24	appreciate 5:15	attempts 69:18
97:22	62:3	appreciated 74:21	attended 10:3
acid 62:14,17,20,23	allergic 5:5,5	approach 13:19 73:9	attention 30:19
acidotic 78:7	allergy 5:10,13	approaching 30:3	Attorneys 2:11,16,22
act 29:10	Alli 39:15,16	appropriate 38:12 99:7	attributed 7:10 62:17
Actavis 1:13 2:14,14,15	Allopurinol 29:15 39:17	arbitrary 32:25	August 11:7
89:5	39:18 62:16	area 8:19 9:16 19:21	authored 9:22
acting 29:16 56:13 87:14	allow 98:9	64:22	authority 88:19
Action 16:10	alter 39:22	areas 19:23	authors 6:10
active 72:20 75:2	alternative 64:3	Argumentative 82:6	automatically 31:23
activities 72:19	amended 54:21,23	arhythmia 78:17,19	52:23
actual 15:24 21:20	American 16:5,6,7 17:24	arhythmias 32:18	autopsy 54:9,14,22 79:18
ad 1:10	18:2	arm 83:5	80:11,18 83:13
added 17:11 19:18	amount 44:16 69:10	arrhythmia 34:9 82:23	available 14:10,13 22:1
addition 50:4	analyses 73:17	83:8 84:5 86:6	31:3 57:1 60:25 81:17
additional 34:5 57:13	analysis 13:16,19 21:9	arrhythmias 27:8 33:8	Avenue 2:17
additive 26:4 48:23	77:19	38:18,20 78:13	average 50:6
addressed 81:3	analyzed 65:23	arterial 44:25	avoid 29:24
administered 56:22	analyzing 14:8	arteries 45:4	aware 26:19 28:18,24
admission 56:21 57:8	anatrophic 30:17	artery 44:20	33:16 41:5 54:2,10
admissions 34:25	Androderm 55:20	article 6:4,8,20,23 7:15	55:12 62:14 63:2 65:6,9
admitted 56:19	and/or 39:1	7:18,21 66:22	79:10 95:19
adonahue@shb.com	angina 45:5 51:20	articles 34:24	awareness 35:16
2:25	annual 19:7	articulated 54:25	A.V 27:7 48:10
advances 20:3	answer 32:9,11,11 35:17	asked 14:16 17:19 20:7	
advancing 23:3	43:23 50:22 62:9 67:11	53:21 64:18 74:12 76:6	B
adverse 20:15,18,19	67:23 68:1,17 76:19	76:9,10,25 79:3,8 89:12	B 3:8
23:20 27:5,10 28:22	81:13 83:3 87:25 91:9	asking 81:13 82:25	back 4:16 29:4 32:21
32:18 52:9	96:6,23	aspirin 53:9 89:24 90:2,3	34:22 41:17,19 42:21
adversely 23:7 35:10	answered 79:8	90:15,20 91:2,8	48:6 66:13 71:13 77:4
advise 45:8,18,25 99:1	answers 4:16 100:7	assess 52:4	85:19 91:16 92:7 98:3
advised 70:12 90:20	antemortem 7:16 50:13	assessing 13:22	99:3,10
advising 74:6	50:17 66:21	asset 76:1	backwards 36:10
affect 35:10 36:20	anti 91:14 94:8	assistant 75:17 89:19	BACON 2:22
affiliate 8:24	antiarrhythmic 57:13	associated 34:6 36:19	based 14:3 44:11 61:8
afternoon 54:20	anticoagulant 53:6,10	54:10	basic 17:1 64:16 85:14
age 23:3 42:17 96:17	90:18,19 91:2,7	Association 16:6	basically 8:8,10 13:3
	anticoagulants 94:16	associations 16:4	basis 10:8 19:7 55:5

83:24 84:9
becoming 28:18
bed 84:24
begun 46:22
belief 100:8
believe 11:7 23:24 42:13
46:16,24 55:2 56:9,19
59:18 65:22 70:12
79:15 87:13
beneficial 52:8 74:7
benefit 25:13 47:20 70:13
70:16 73:17
benefits 21:10
BERTEK 2:20
best 10:25 11:1 14:1
28:11 35:3 40:9 44:23
63:8 65:2 83:10 85:13
95:11 96:7,8,9 100:7
beta 26:4 55:21
better 45:21 56:1 74:15
74:24 75:9 91:9
beverage 26:18
beyond 17:1
BID 58:1
big 83:18 85:12
bill 99:22
billed 11:21
billing 99:21,23
bit 10:20 41:10 61:13
65:5
bleeding 68:22 83:11,12
block 27:7,8,13
blocker 25:5 55:21
blockers 21:4 26:4
blood 26:20,25 44:14,15
44:17,22 49:10 50:25
52:23 65:23 68:25
77:12,15 87:14 88:12
88:12
bloodstream 38:2
blood/femoral 50:6
board 9:5,7,9,10,11,12
body 36:8
books 22:17
born 8:18 44:13
bothered 92:11
bothersome 27:21
Boulevard 2:23
bouts 27:18
bradycardia 27:7
brain 44:3
branch 27:8,13
branches 16:10
break 44:2 49:3 85:17
breaks 48:17,18
breath 28:25 74:20
brought 13:8 41:18
Brown 22:8,11
BUN 39:1,5,12 61:4,5,8
78:5
bundle 27:8,13
BUNs 64:23 65:4 77:18

C

Ca 2:12,23
calcium 21:4 25:5 38:14
38:23
calciums 77:19
calculated 61:4
calculation 61:7
California 1:19 2:4,5
8:15,21 9:16 12:11 77:4
100:1 101:1,7,20
call 10:22 11:16 29:5
32:22 54:6 68:2 75:3
94:19 99:17,17
called 18:10 23:14 89:5,8
92:24
calls 10:22 81:23
Card 18:3
cardiac 24:5,11,20 26:5
30:18 32:18 38:21
42:23 43:9,20 44:4 46:7
68:15
Cardio 18:10,12,15
cardiologist 15:1 31:5
47:24 59:2 65:21
cardiologists 17:10
cardiology 8:25 9:7,10,13
9:14,15 13:1,3,3,4,6
16:6,7 17:8,13,24 18:3
18:4 19:15,24 22:4,7,8
22:10,14 23:5 24:20
40:15 76:3
Cardiovascular 9:8
cardioversion 56:19,22
57:10,11 71:8,12
care 75:24
cared 95:15
career 24:21 31:12 65:21

66:4
carefully 87:3
carried 41:22
carries 13:10
carry 21:1
case 7:3 10:14,18 11:8,22
11:24 12:8 25:2,7 28:10
28:16 29:6 30:18 42:25
79:20 85:9 89:1 99:18
cases 5:9 10:11 33:16
71:2 83:21
catheter 69:21
catheters 94:12
cause 7:10 38:12,17 41:7
42:25 43:1 44:4,7 54:25
62:23 63:5,9 65:1 72:13
76:7,12,22 82:12,21,22
83:19 85:9 96:19 97:3
caused 27:3 41:2 86:6,24
causes 44:22
causing 69:22 86:5
caveats 97:3
CBC 14:18
cells 38:3
center 8:23 15:12,15
Central 8:15
certain 13:18 14:9,13
35:9 44:15 63:22 86:12
86:12
certainly 4:17 15:19,23
18:19 19:16 31:7 33:11
38:13 43:3 45:16 47:14
60:8 75:9 78:3 84:25
91:15 94:13,22 95:13
96:3
certificate 53:18 54:10,17
54:22 79:19 80:11,19
100:4 101:4
certification 13:9
certified 2:4 9:5,7,9,13
13:2 101:6,24
certify 101:8,17
chambers 94:21,23
chance 44:1 73:12 92:9
97:19
change 29:5 36:22 47:9
80:18 82:4 93:1
changed 79:18,23 81:21
changes 20:4 32:19 34:3
99:2,5,7,8,9

changing 55:6 80:10
channel 21:4 25:5
chapter 30:24
CHARLESTON 1:3
chart 5:17,18 25:22
41:10,11,24 54:5 57:4
57:18
charts 61:8
check 37:16 40:20 42:22
42:23 56:8 60:7 70:11
77:17 87:3 95:4
checked 29:7
chemical 31:13
chemistry 14:19 77:10
chest 47:11,13 58:23
chewing 45:25 46:6
Chief 57:23 58:3,20
choice 64:5
choices 64:4
cholesterol 14:19 45:20
45:21
choose 83:6
chosen 90:22
chronic 36:12 46:24,25
47:14 58:18
chronically 37:8
Cindy 1:22 2:4 101:6,23
circumstances 4:25 6:3
8:12 40:24 51:22 66:7
83:10 86:13 96:16
cite 30:23
Cities 56:18
claiming 40:16
clarity 58:15
class 10:4
classified 46:15
classify 46:14,17
clear 4:22 65:17
clearance 35:23 39:21
87:16
cleared 23:21,23,25
Cleveland 2:17
clinical 31:17,24 32:2,17
33:4,22 34:14 37:1 45:6
52:18 62:21 67:21 79:4
86:15 95:24 96:17
clinically 35:4 68:5
clipped 96:13
close 38:4 95:12
clots 44:1,2 53:3,13 94:12

CME 12:21 19:3,6,14
coagulation 91:14 94:8
Coastal 17:8,13 76:3
Coe 7:15
coincidence 34:13
College 16:6,7 17:24 18:3
Com 18:10,13,15
combination 39:6 70:19
87:4
combine 48:21
come 32:21 34:15 35:7
77:4 85:19
comes 57:9 77:1
comfortable 28:17
coming 5:15 12:6 15:25
34:24 37:4
commencing 2:6
comment 71:24
commercially 31:3
commit 92:18,18
committed 92:21
Committee 16:10
common 24:10 34:4,18
47:24 73:7 88:7 94:17
97:2
commonly 24:7 26:17
37:2,2 38:21 72:15 84:3
86:14,19
communicating 31:20
communication 75:20
communities 70:3
company 20:13,19 85:6
compared 6:16
comparing 73:3
complain 47:17
complains 72:7,25
Complaint 58:3,20
Complaints 57:23
complete 33:20
completely 35:13 56:15
complex 34:5
compliant 95:10
complication 43:16
complications 28:9
composed 6:16
composition 54:7
computer 5:18 49:25
76:5
computerized 101:15
concentration 31:21 33:3
33:12,15,21 60:6 65:7
concentrations 33:7
61:24 67:9,17 87:2,23
concern 40:22
concerned 90:21 94:11
concerns 57:12
conclude 52:24 59:1
concluded 99:25
conclusions 13:25 15:25
concomitant 26:3
condition 73:3
conduct 48:8,10
conduction 26:5 48:12
congestive 30:16
conjunction 46:19
consider 17:5 32:13,19
considered 32:5 64:12
consistent 26:6 27:10
42:17 95:13,25
consistently 15:13,15
55:10 61:15,20 62:6,13
63:1
consult 22:23 70:9
consultant 20:12
consultation 11:22 69:14
consulted 10:11 90:23
consumed 26:18
contact 92:22
contain 26:18
continued 55:15
continuing 12:16
contractility 30:17
contributing 86:5
control 23:11 25:11,12
47:19,23,25 48:4,15
51:19 70:20
conversation 22:3 52:17
86:7
conversations 6:1,5
19:19
copy 5:23 8:9 49:21
Corner's 54:4
coroner 53:22,25 54:9,19
79:17 80:10,18
coroner's 81:4,19
corpse 69:1
correct 13:20 14:4,25
15:7,17 16:2 18:5 20:4
21:22 33:5,10,14 35:23
36:5,15,25 38:1,5 39:9
40:2,3 48:22 49:23
51:24,25 52:6 53:1
55:16 58:24,25 59:9
60:4,5,14,17,18 61:10
61:11 67:19 69:7 73:6
77:16,21 78:1,20,21
79:6,7 80:8 84:7,11
86:20,22,23,24,25 87:7
88:4,5,8,9,13,14 89:14
89:25 90:1 91:23,24
93:13 94:4 97:13
101:18
corrections 99:2
correctly 7:11
correlate 59:16
Correlation 7:16
Coumadin 53:14,16
90:20 94:5
Counsel 2:9 50:20 98:10
counted 72:4
counts 19:17
county 8:23 16:5 53:21
53:25 54:3 70:2 79:18
100:2 101:2
couple 13:7 20:2 22:23
29:18 40:19 83:15
89:10 98:5,6
course 14:22 25:3,4 73:1
court 1:1 4:18 32:10 98:3
99:3,10
cover 56:14,15
covered 56:3
covers 56:4
crayons 83:18 85:12
creatinine 39:1,6,12 61:4
61:5 78:5
creatinines 61:8 65:4
77:18
creation 41:24
criteria 45:15
critical 93:24
criticisms 15:21
cross 10:10
Cruz 53:21,25 54:3 79:18
CSR 1:22
cup 73:12
current 19:1,13 20:8
57:24
currently 41:1
Curriculum 3:10
cut 35:19
C.V 9:20 40:2,8,13

D
D 1:22 2:4 3:1 101:6,23
dae@emlaw.us 2:13
dale 72:21
damage 45:6 69:22
Dan 9:24 11:24 27:16
41:10 42:5 48:4 49:11
53:19 54:3 67:14 69:9
69:13 70:9,14,15,18
71:4,19 72:6,13 82:12
82:21 95:6,9,15
Daniel 1:8
data 13:24 14:3 15:20
20:6,7 64:16 81:16
date 69:14 80:2 82:4
89:16
dated 3:11 49:9 100:10
101:20
dates 34:22 95:4
David 42:8
day 54:20 55:11,23 56:6
56:6,7 57:3 58:16 59:19
59:22,23 60:13 67:22
68:6 73:24,25 79:5
84:24 86:20 100:10
101:21
days 29:4,12 49:20 59:24
66:4
day-to-day 72:18
deal 57:15 58:17 60:10
60:11
death 7:10 9:24 21:2
28:11 43:9,20 44:4
53:18 54:8,10,17,22
55:1 67:10 68:8,15 69:2
76:8,12,23 77:16 78:7
79:18 80:11,18 82:12
82:18,22,22 83:8,19
84:16,21 86:6 95:17,25
96:17,19
decade 25:19
decided 93:1
decision 15:4,7 21:8
93:15
declare 100:6
decline 64:20
deconditioning 73:6

decrease 36:3
decreases 39:21
deem 99:7
DEFENDANT 2:14,20
defendants 1:14 3:9 40:5
49:12 89:1,3,5
defibrillation 71:13
definition 45:13
degree 27:2,7 63:11,12
63:21 64:25 66:19
82:20 87:6 88:10
delayed 71:25
demonstrate 62:8
demonstrates 74:8
depends 24:7 60:18
73:12 76:25
depletion 36:15
deposed 54:19
deposition 1:17 2:1 4:10
5:1 7:2,6,15,25 77:1
98:8 99:25 100:7
101:13,17
depositions 99:19
deputy's 68:1
derivatives 34:6
desired 44:16
desks 75:18
destroyed 42:1,2
details 5:14 11:18 20:17
92:8
detected 33:8
determine 32:10
determining 39:3
develop 44:2
developed 69:19 74:17
deviated 95:14
diagnose 31:23 52:10
diagnosed 31:9 42:16
60:3
diagnosis 15:7 32:6 33:20
die 83:6
died 6:16 54:4 66:11,12
67:14,18,22 77:25
78:24 80:20 83:16 96:4
difference 43:18
different 6:3 8:11 16:9,11
16:11 19:23 23:11 30:9
30:10,22,23 32:3,21
48:4,21 51:14,15,21
56:8,12 88:5,6 89:23
91:7
difficult 5:2 43:19
digitalis 7:10 11:19,19
26:4 29:2,9,19,25 30:15
31:13,14,17 32:13,16
32:21 34:1 35:1 36:11
36:19 55:2 56:4,6 83:7
83:15,19 84:1 96:4 97:2
Digitek 1:5 8:7 18:13
40:17 41:1,2 79:11
95:20
digitoxin 33:25
digoxin 6:2,15,21 7:17
8:3,6,11 18:16,23 21:6
21:19 22:24 23:25 24:3
24:13,17,19 26:9 27:17
27:23 28:9,22 29:22
30:10 31:9,21,23 32:1,5
33:3,4,7,12,15,17,20,21
34:7,18 35:4,8,23 37:7
37:18,19 38:9,12 39:9
39:19 41:6 47:21 48:25
55:11 56:23 57:2,14,15
60:3,6,14 61:16,23 62:3
65:6,11 66:5,8,16,20
67:14,17,22 68:5 69:9
69:10 70:20 73:24 79:5
82:16 84:5 85:25 86:21
87:1,10,15,17,22 88:7
88:11 96:1,15
diltiazem 18:18 21:19
23:23 24:24 25:5,8,16
26:2,3,8 27:6 47:19
48:24 50:1,4,12,13,17
51:4,9 52:11,14,19,21
56:5,7 66:1 70:20 74:4
74:25 86:4,4,9,10,14
87:1,6,9,12,14,16 88:1
88:4
diminish 23:2
direct 82:22 92:22
direction 90:16
directly 98:21
disagree 50:9 62:18
discomfort 47:11
discuss 92:1
discussed 11:24 91:19
discussing 93:11
discussion 23:16 27:15
28:7 53:24 92:5
discussions 71:3 92:17
disease 5:11 14:9 21:24
23:11 44:25 53:12
72:12 94:15
diseases 9:8 23:6
distress 68:2
distributed 37:25
distributing 89:3
distribution 36:8 84:19
86:8
distributor 89:7
DISTRICT 1:1,2
diuretics 36:22 39:24
divided 56:16
DIVISION 1:3
dizziness 28:24
doctor 66:25 67:2 94:24
document 1:7 99:1
documents 5:21
doing 58:22 72:18 78:23
Dollen 1:17 2:1 3:4 4:1,9
49:8 88:24 97:17 100:6
100:14
Don 2:12 99:17
Donahue 2:24 3:5 88:23
88:25 89:9 93:17 96:21
97:7,16 98:24 99:5,11
dosage 52:20 56:16
dose 31:2 36:12 37:18,21
52:24 55:15,15,24 56:1
57:5 58:10,13,15,18
60:13 61:16,17,20 62:6
67:14 69:9 74:25 83:15
84:25 85:4 86:15 95:14
doses 35:5,8,13 41:8
48:22 55:11 56:7,12
57:2,8 83:17
dosing 55:22
Dot 18:10,12,15
double 58:10 60:13 62:6
doubled 58:4,9 59:18
doubling 58:18
dozen 66:6
dozens 31:15
Dr 5:23 6:6 7:2,6,9,15
42:7,8,12 49:8 54:19
55:5 62:17 66:22,24
69:13,16,20 70:5,9,15
73:8,14 74:5,11,14 75:8
79:17 81:21 88:24
90:23 91:9 92:7,22 93:7
94:7 97:17
draw 37:7,12,13,18 66:13
77:12
drawn 6:17 37:20,23
40:22 69:1,5,6 77:15
84:21 88:13
draws 65:7
drew 78:18
drift 7:9
drive 36:9
dropping 44:17
drug 5:5,13 20:18 21:9
23:20 25:19 29:15
34:21 35:5 36:8 37:10
37:14 47:25 56:12
65:14
drugs 12:22 21:23 22:19
23:20 30:2,21 36:7 37:4
48:4 71:1
due 44:20
duly 4:2
dutifully 84:23
dynamics 6:25
dysfunction 35:15 37:5

E

E 1:8 3:1,8
earlier 33:24 37:23 42:22
47:12 55:19 78:12 84:9
87:25 96:6
early 31:5 42:20
easily 84:4
easy 56:6
echo 70:15
edition 22:22
education 12:16 16:12
20:1
effect 29:11,25 30:17
52:8 55:25 86:12 87:20
effective 74:15
effects 12:23 26:5 52:9
efficacious 48:20
efficacy 74:18
eight 42:3
either 5:22 19:7 26:1
40:20 60:12 73:21
78:15
EKGs 67:16
elder 39:13

elderly 37:3 60:20
electrocardiogram 33:9 78:22
electrocardiograms 15:2
electrocardiographic 33:22
electrolyte 36:17 38:7
electrolytes 77:24
electronic 41:25
electronically 41:14
electrophysiological 12:23
electrophysiology 19:23 69:21
elevate 26:9 87:1,15
elevated 32:22,24 33:2,6 33:12 35:4,7 36:24 37:24 38:3,11,17 39:5 43:24 45:19 52:22 61:21,25 62:14,17,20 62:23 63:1 64:23 83:19 84:2 85:9 87:7
elicit 76:17,21
eliminate 70:25
ELIZABETH 2:14
ELLIS 2:16
embolis 68:23
emergency 31:16 34:15
empty 73:13
enables 18:11
encounter 66:8
encountered 52:21 66:1,5
energy 29:1
English 4:15,17
enhance 38:13
enlightened 11:14
entitled 7:16 77:2
envelope 98:22
epidemiology 16:17
episode 59:7
equating 64:10
era 35:2
Ernst 2:10,12 3:6 6:1,7 7:2,18 9:25 11:21,25 32:7 49:2,5,17,19 50:19 51:10 52:14 55:4 59:4 60:15 62:9 63:15,24 66:22,24,25 67:2,5,23 68:11,16 70:21 76:6,9 76:19,24 77:6 79:8,10 79:19,21 80:12,21 81:10,23 82:6,11 84:12 93:22 96:5,14,23 97:4,8 97:14 98:5,9,14,17,25 99:6,14,23
essential 44:9
estimate 24:16 96:9
estimated 39:1
et 1:13
etiology 38:8
Euclid 2:17
Eugene 4:9
evenhanded 73:9
event 10:16 20:15,18,19 23:20 78:9
everybody 84:19
evidence 33:22,23 45:1,7 69:8 78:15,20
exact 7:21 56:12
exactly 16:15 18:5 73:15 73:18
exam 14:23
examination 3:3 4:5 88:21 93:20 95:24
examined 4:3 101:9
example 14:6 15:12 62:7
exceed 21:10
excess 69:10
excessive 31:14 52:24
exercise 47:15 74:23
exert 12:22
exerting 87:19
exertion 72:18
Exhibit 7:14 40:4,5 49:6 49:9,12 66:3 80:3 87:8
exhibits 7:1
expect 29:19 56:5 62:7 67:12 86:16 87:19
experience 26:6,8 27:11 95:23
expert 10:12 15:19 17:5 79:19
expertise 69:20 70:1
experts 19:20
explain 29:9 84:25
explained 67:20
explaining 85:11
express 53:15 64:16 76:7
expressing 63:13 82:12 85:8
extended 22:2 58:19 60:9
extent 7:13 38:25 83:21
extra 58:12
e-mail 40:1 41:11
e-mailed 9:20

F

fact 11:18 12:6 29:9 65:2 72:9 73:14 74:11 82:9 84:1,1,2 85:14 86:3
factor 86:5
factors 43:18 46:20
facts 95:22
faded 13:9
failure 13:11 30:16 41:7 73:16
fair 50:14 59:1 64:20 68:7
fall 71:4
familiar 46:9
family 22:3
family's 68:2 95:13
far 8:11 11:14 16:11 19:24 24:13 30:1 31:13 32:18 40:20 45:5 49:4 61:5 75:3 77:22 86:18 88:18 90:21 91:11
fast 28:23 43:6 75:2 97:21,21
faster 28:16 74:22
fatal 33:13,16
father 72:25
fatigue 29:1 47:17 72:7 72:13 74:20
fatty 63:8
favor 98:11
faxed 54:2
FDA 41:1
February 57:18,19
feel 47:10 56:1 58:12
feeling 34:16 59:13
fellowship 8:25
fellowships 9:2
felt 34:24 44:24 58:20,21
fib 42:20 47:7 48:5,15
fibrillation 13:13 14:6 21:25 25:10 27:19,20 27:21,25 28:1,5 29:21 42:16,25 43:4,8,12,13 43:21 46:10,15,18,18 46:24 47:9 48:1,8 53:2 53:5,9 57:10,16 59:8,14 69:17,19,23 71:9 72:8 72:12 73:20 94:14
field 69:20 70:7 75:5
Fifty-nine 8:14
file 89:11 98:3
files 81:20
filtration 36:4 39:2
find 18:13
finding 96:15
fine 75:3 83:4 94:23 98:23
finished 50:20
firm 84:14
first 4:2 11:7 27:7,18,23 27:25 28:4 37:5 53:13 57:24 58:16,21 65:16 79:23
five 12:21 29:12 31:18 61:2 74:14 77:24 79:10 85:18
fixed 87:4
flip-flops 58:22
floor 30:4
focused 47:21
folder 85:22,25
following 37:18
follows 4:3
food 26:18
forcing 83:5
foregoing 100:7 101:10 101:17
forensic 82:14
forever 85:5,5
form 64:13 91:1 96:22
format 7:22
forth 11:20 43:16 101:14
found 23:6,9 43:1
Foundation 16:8
four 29:12 77:4
frail 39:13
frames 11:5
Francisco 2:23 8:21
frequent 75:19
frequently 37:13
Friday 7:3,7
friends 19:22
front 99:2,9
full 4:8 73:13 101:18

function 23:2,7 35:11
36:21 95:7
further 98:18
fuzzy 10:20 11:17

G

gather 13:23 15:5
general 6:14 10:4,6 11:5
12:3 13:4,15 20:25
21:24 22:8,14 23:2 25:3
25:4 37:19 43:25 67:8
73:19 86:1 88:17
generally 21:17 28:4 30:2
genetic 44:11
gestalt 37:2
gestures 4:19
getting 37:1,14 55:10
57:25
GFR 39:6 60:20,22,25
61:3,6
Gilman 8:9 22:20,22
65:19
give 11:5 21:13 48:21,24
48:25 56:15 57:13,15
76:10,17 82:25 86:12
92:7
given 57:8 62:21 86:3,14
glanced 6:22
glomerular 36:4 39:2
glycoside 24:20
glycosides 24:5,11 34:1
go 8:20 10:9 15:14 28:1
28:14 32:11 35:21 44:2
44:19 47:8 49:24 52:8
56:5,10 59:4 62:9,21
64:2 66:13 67:23 68:16
72:20 75:23 78:7 80:23
90:22 91:1,7 92:7,13,15
93:4,6 96:23 98:12,19
goes 11:15 36:5 41:19
44:18 58:17
going 4:14,15 9:20 15:21
28:16 29:24 30:7 33:19
34:16 37:3,4 38:16
41:17 42:21 49:2 58:22
61:6,13 71:5,6,14,17
74:22 76:21 77:6 78:9
91:16 97:18 98:19
99:18,19
golf 72:25

good 21:17 24:9 28:17
48:18 49:4 61:5 73:8
97:23
Goodman 8:8 22:20,22
65:19
gout 39:15 62:18,20
Grand 2:23
granting 16:12
grants 16:12 40:11
great 95:1
greater 31:22 64:11
74:17,18
greatest 19:25
grew 8:18
Griffith 1:22 2:4 101:6
101:23
group 17:8,10 42:9,9,13
grow 8:15
growth 19:15
guardian 1:10
guess 24:18,18 32:12,24
33:17 36:14 37:1 42:3
48:2,16 52:18 63:19
64:3 65:16 69:24 71:18
81:9 83:10,21 85:13
96:8,8
guessing 81:12
guidelines 46:10 53:8
guy 39:11 70:6 83:18
84:3
guys 39:14 65:4
guy's 72:9
G.I 34:11 68:22 83:12

H

H 3:8
half 45:12 66:6 73:13,13
83:22
hand 4:19 19:16,18 21:20
21:25 62:21,22 85:16
handouts 21:13
Hands 58:21
hands-on 95:23
happen 35:12 64:5,21
68:22 70:5 80:14
happened 8:9 22:23
41:23 48:12 54:12
78:19 84:7
happens 42:21 43:1
44:10 47:8 62:25

happy 92:10 98:17
hard 5:3,22 61:7
HARDY 2:22
harm 41:3
Harvey 42:8,12
hat 44:13
head 4:19 35:18 36:16
37:11
healthy 65:3
hear 76:19
heard 6:18 20:16 54:12
80:10
heart 12:23 13:11 14:9
21:14 28:1,13,15,23
29:15 30:1,3,16 34:16
43:6,17 44:3,25 50:6
53:12 58:12,22 70:20
74:21 75:1,25 94:8,15
94:21,22
heavier 45:16
held 23:16
help 57:16 92:14
helpful 75:1
Hennepin 8:23
hepatitis 63:6
hesitance 53:16
high 10:3 15:15 78:8,16
85:5
higher 32:17 43:15 44:15
44:18,22 46:3 48:21
57:2,5,8 61:13 65:5
72:17 74:25 84:20
hill 72:21
history 14:23 58:8 96:17
holding 7:1
holter 74:1
home 22:5 35:14
hope 15:23,24 27:24
Hopefully 64:17
hospital 34:25
hospitalizing 56:17
hour 2:6 49:2
hours 19:6,9 29:18 37:20
55:25 56:3,4,14 67:18
69:5,6 77:15 83:15
84:20 88:11 99:21
huge 88:18
hunting 72:1 93:4,6
Hurst's 22:10
hypertension 23:6 44:5,8

51:18 53:11
hypotension 27:8
hypothetical 15:4
Hypothetically 15:18

I

ideal 45:17 82:2
identification 40:6 49:13
idiopathic 46:17
ill 66:11
illness 35:22 36:13
illnesses 35:11 36:7
imaging 14:13,17 15:12
15:14
imbalances 38:7
immediate 29:20 94:2
impact 23:7
impaired 37:5 95:7
imply 58:18
important 20:4 38:8
64:14
inaccurate 59:12
inadvertently 60:12
incidence 46:3
incident 58:6
include 21:4,6
including 21:2 27:8
increase 23:19 24:3 35:23
39:8,19 43:8 87:22
increased 30:17 46:6
increasing 74:3 75:4
independent 42:4 64:21
Inderal 29:16
index 52:3 86:9
indicate 41:16 55:9 62:3
67:21 92:25
indicated 76:2
indicates 27:6 78:23
91:25
indication 92:20
indicators 66:20
individual 1:8,9 48:6
78:10
infarction 14:8
inform 11:8
informally 10:10
information 15:9 19:24
21:25 26:13 51:6 67:13
86:17
infrequent 46:22

Initially 47:8
initiated 25:19 27:23
 41:21
injuries 40:17
injury 44:19
INRs 14:19
insert 8:3
insight 27:4
instances 30:9 66:8
insufficiency 23:19 24:2
 36:5 39:8
intend 28:12 76:16,17
intending 76:10
intensive 75:24
intent 70:22
intentionally 60:12
interest 44:23
interests 12:25
intermittent 47:4
intermittently 27:20
internal 9:5,12 17:2,3
internship 8:22,24
interrelated 5:12
interrupt 50:20
Interruption 59:5
intervene 35:11
interventional 9:14 13:3
 13:6 19:23 22:7
intoxication 55:2 83:8
 97:2
intracranial 83:11
involved 6:25 11:9,14
 96:7
involving 30:21
in-depth 6:24
in-person 11:6
issue 8:11 28:19 93:24
issued 54:9,21
issues 11:9 64:19
Item 49:24
items 91:18,18
I.V 56:22 57:8,15

J

J 1:9 2:24
Jesse 75:12,17 89:18
 91:19
joined 42:9
Jose 54:20 69:25
journal 17:24 18:2,4,4

journals 6:12 17:23
 18:11,25 19:14,25
Jr 1:8
July 74:3
June 3:11 49:9 64:24
 72:5 80:4 81:20

K

Kathy 1:8 71:21
keep 12:19 20:4 22:4,17
 22:19 30:5,21 41:13
 57:20 72:25 75:1 85:22
 85:25 98:2
keeping 19:13,14
kept 41:24
kidneys 23:21,23,25
kind 13:8 39:14 40:1 93:7
knock 94:12
know 4:22 10:2,25 16:9
 20:15,16 22:22 25:18
 25:20 27:12 29:4 32:22
 35:9 36:24 39:15,18,20
 39:21 42:2 44:12 45:15
 51:20 52:5 54:12,25
 55:5 59:24 60:8 61:1,3
 61:9 63:6,9 66:11,19
 68:24 69:4 70:5 71:19
 77:3,14,22 78:3,5,18
 79:17 80:15 81:13,16
 82:14 83:16 84:6,10,14
 84:16,22 85:4,6 86:8,9
 88:1,1,2,17,18 90:10,14
 91:12

knowing 73:15 96:11
knowledge 19:17,18
 26:16 39:25 40:18 46:5
 64:22 81:8 94:25 95:6,9
 95:11,24 100:8
known 10:6 87:22

L

lab 3:11 50:3 51:6 60:25
 65:13 79:24 80:2,25
label 24:24 26:2 27:6
labeled 69:10
laboratories 2:21 30:10
 79:12 88:5
laboratory 14:10 26:21
 32:5 84:15
labs 14:18 30:22 49:25

50:11 82:15
Lab's 49:9
lack 29:1
Lanoxin 8:7 57:25 58:4,9
 59:19
large 94:13
Law 2:11,16,22
Lawrence 1:17 2:1 3:4
 4:1,9 100:6,14
lawsuits 81:12
lead 52:24 60:14 68:4
leading 70:7
learn 19:19
led 52:17
left 42:13
Lemm 7:6,9 62:17
Lemm's 5:23 6:6 7:2,15
lesion 46:3
lessen 28:6
lethargy 29:3
letter 82:11,11 99:11
letters 10:14
Let's 31:19 41:9 56:10
 59:4 68:10,13 85:17,18
 91:5
level 29:13,22 30:1,3,8
 32:14 36:24 37:18 38:5
 50:12,14,17 51:8 52:6
 52:15,22 57:14 60:6,22
 60:23 61:21 62:24
 63:22 82:16 83:19 84:6
 85:9 86:4 87:4,7,10
 87:15 88:8 90:2 96:15
levels 6:2,15 7:17 8:11
 14:19 26:9,24 29:7
 31:14 32:16,21 33:17
 35:4,7,23 36:9 37:7,12
 37:20,23 38:11,17,23
 39:13,19 40:20,22
 50:25 51:4 52:21 62:14
 62:18 63:2 65:23 66:1,5
 66:9,13,17,20,21 72:17
 78:7,12 82:18 84:11
 85:5 88:3 95:12
LIABILITY 1:5
library 22:5
licensed 12:10,13
life 28:11 38:20 61:2
lifestyle 53:16
light-headed 58:22

light-headedness 28:25
likelihood 41:2 73:9
limitations 30:2 48:24
limits 79:16
line 58:3
lipids 45:19
list 64:4
litem 1:10
literature 9:21 19:1 41:6
 65:18
litigation 1:6 76:8
little 10:20 13:7 41:10
 61:13 65:5 80:17 81:22
 82:5
live 43:7
liver 63:8
living 6:17 52:6 88:3,8
LLC 1:13 2:14,15
LLP 2:16,22
logistical 12:7
lone 46:17 53:8
long 5:2,14 9:15 36:12
 43:7,12 49:19 55:24
 56:4,13 66:18 70:5 71:9
 86:16,22 91:15 94:14
longer 90:11
long-term 71:10
look 5:17 18:12,25 25:22
 28:21 39:3 42:24 44:21
 57:22,24 76:4 87:24
 95:22 98:14
looked 8:2,8,10 18:15
 24:23 40:25 51:8 52:13
 65:22
looking 29:23 30:16,25
 57:17,21 59:2 60:24
 65:19 66:3 73:23
looks 41:12 90:5
loose 94:12
lose 44:2 45:8,18
loss 57:12
lot 19:17 34:7 45:23
 52:19 68:21 86:18
 92:16 94:9,19 97:20
love 86:16
low 39:6,13 57:14 74:13
lower 30:1,19 45:21,21
 53:13 58:17 60:20
 87:10
Luis 1:19 2:3,12 5:16

69:25 100:2 101:2,20
lying 8:9

M

mail 99:6
main 39:4
major 36:13 39:22 46:19
53:12
majority 71:2
making 15:4 21:9 50:21
Malone 75:12,17 89:18
91:19,25 92:5 93:10
malpractice 15:19
man 72:13 83:6
management 46:10
manifest 32:3,17 34:10
manner 87:15,20,21 96:4
manufacturing 89:4
mark 40:4 49:6
marked 7:14 40:5 49:8
49:12
markers 61:5
Mason 54:19 55:5 79:17
81:21
mass 65:5
MATTHEW 2:18
matthew.moriarty@tu...
2:19
MATTISON 2:10
McCornack 1:8,8,9 5:18
9:24 25:13 26:14,22
27:16 28:8 39:10,24
41:10,17 42:5,15 44:5
44:24 45:8 49:11 51:7
52:10 53:10,19 54:3,17
55:9 56:18 57:2 61:1,24
62:13 63:1 64:23 67:14
69:9,13 71:4 72:6,13
74:19 75:15 80:19
82:11 86:19 89:13,23
90:22 91:21 92:10 95:1
95:6,9,15,24
McCornack's 11:24 25:7
46:14 48:4 50:12 54:8
73:19 76:8,22 77:15
78:16 79:11 82:12,21
86:3 92:2
McDaniel 2:2
MDL 1:8
mean 12:5 14:18 18:19

22:6 29:10 32:8 33:3,7
43:24 46:6 50:19,24
58:8 63:22 74:10 77:12
82:5 93:25
meaning 52:4 66:16
84:10
meaningful 78:8
means 32:9 44:9 97:18
meant 65:18
measure 43:19 86:11
measured 87:11
measures 39:2
mechanism 36:1
medical 5:9 8:20,23 9:21
12:16 13:17,19 15:19
16:3,5,5 17:23 18:25
19:1 22:5 27:3 34:23
41:5,13,18,20 45:13
54:2 60:24 62:2 63:11
63:13,21 64:25 65:18
72:5 75:17 76:11 82:10
82:21 89:19
medication 39:16 58:11
74:25 84:23 85:7 87:5
95:10
medications 20:21,23
21:1,14 23:11 26:1,15
35:22,25 55:18 57:25
75:4 89:23
medicine 9:4,5,12 12:10
12:13 17:2,3 20:3
medicines 35:10 36:22
92:11
meet 10:22
meetings 11:6
member 16:3
memory 10:25 11:1 42:4
42:17 56:25 65:25
71:20
mention 57:4
mentioned 13:2 35:15
42:7 52:16 55:3,4 79:13
83:14,25 84:17 97:3
met 9:25 10:17,21 27:18
45:13 88:24
methods 13:16,22 15:25
mid 31:6
mild 44:6 53:11 90:19
94:22
mildly 32:22,23

military 17:15
milligram 31:2 55:11
59:21,22
milligrams 55:10 58:1
milliliter 84:11 96:16
mind 43:5 45:16
minimal 28:11
Minnesota 8:24
minor 1:9
minutes 77:24 85:18
99:22
mistake 98:1
mixed 29:5
mixture 34:1
moment 5:7 54:6 78:9,23
Monday 1:18 2:6
monitoring 74:2
month 8:4,14
months 22:23 77:5 91:14
Moriarty 2:18 3:4 4:7
23:17 33:1 40:4,7 49:6
49:14 51:2,12 59:7,10
60:16 62:12 63:18 64:1
67:1,3,7 68:3,12,19
70:24 76:21 77:2,9 79:9
80:1,16,22 81:11,24
82:8 85:2,17,21 88:15
89:4,7,12 96:2,13,20,22
97:15,17,25 98:7,11,23
99:16
Moriarty's 96:7
mouth 55:3
MRIs 15:13,15
multiple 37:3,4
muscle 30:18 36:12,13
38:2 65:5
muscles 94:22
muscular 39:11,11,14
65:4
Mylan 2:20,20 89:1,8
myocardial 14:8 45:6
M.D 1:17 3:4 4:1 100:6
100:14
M.I 82:23
M.I.s 83:12

N

N 3:1
name 4:8 6:8 18:1,5
88:25

named 101:10
names 16:11
nanograms 84:10 96:15
nature 14:20
nausea 29:3 32:19 34:3,8
necessarily 31:25 32:23
33:7 36:20 46:19 58:18
67:9
necessary 91:1
neck 58:22
need 4:16 23:10 24:7
48:3 70:25 84:6
needed 48:14,17 91:6
94:2
negligence 5:9
neither 97:16
nephrology 16:25
never 35:13 43:5 65:24
86:24
new 19:18 46:9 54:25
night 79:5
nine 64:23
NMS 3:11 26:21 49:9,25
50:3,11,18 79:12 82:15
node 48:7,10,13
nods 4:18 35:18 36:16
37:11
nondigoxin 34:5
nonissue 29:8
nonmedical 69:18
nonsteriodal 36:21
nope 72:2
normal 30:10 35:5,8
43:17 50:13,17 60:22
65:2 69:23 79:15 94:9
94:23
notation 92:4
notations 72:3,4
note 25:25 42:6,7 57:17
57:19,22 58:17 70:9
89:12 90:7 91:17 92:7
98:1
noted 75:1
notes 5:23 6:6 41:16,16
41:21,24 55:8 57:4 71:7
71:24 72:24 73:1 76:3
89:11 90:12 101:19
notice 26:24 72:22
noticeable 72:17,19
noticed 47:13,15

notification 10:16
notorious 59:13
notoriously 59:12
November 25:25 46:16
 71:24 72:6 75:16
nuclear 9:4,10 13:2
numb 58:22
number 19:22 23:10,10
 30:19 32:3 40:23 45:22
 49:25 51:24 52:5 64:5
 72:3 84:2,20 87:4 89:23
 91:25 95:1
numbers 30:23 51:17
 75:8
numerous 18:11 22:6
 69:18
nurse 75:13,24

O

obese 45:16 63:7
obesity 45:13
Obispo 1:19 2:3,12 5:16
 69:25 100:2 101:2,20
objection 32:7,8,10 50:21
 50:21 51:10 60:15 62:9
 63:15,24 67:23 68:11
 68:16 70:21 79:8,21
 80:12,21 81:23 82:6
 84:12 96:2,20,21 97:7
observations 96:18
observed 86:15
obstruction 44:20
obvious 83:19
obviously 12:5
occasion 43:6 45:24
occasions 45:22 64:24
occur 27:21 28:6
occurred 11:6
occurring 57:16
occurs 84:18
October 1:18 2:6 101:21
odds 73:16 74:13 92:13
offer 27:4 73:11
offers 75:10
office 5:17,18,23 20:10
 22:5,9 25:25 41:21 42:5
 54:2,4 57:19 72:6 75:14
 75:15 76:2 81:1,4,19
 89:14 92:6,25 93:10
offices 2:2

oftentimes 72:19
OH 2:17
Ohio 41:18
Okay 4:17,19,20,23 5:15
 5:25 7:24 9:2 10:6,17
 11:12,21 13:22 16:14
 18:12 20:2,10 21:1,18
 22:4 26:2 27:15 28:7
 29:21 31:8,19 32:1
 34:18 36:17 37:17
 38:14 39:5 40:1 41:9
 42:12 43:20 48:18,20
 49:1,5 51:3,6,13 52:10
 53:15 56:17,25 57:7,18
 57:22 59:11,17 61:19
 64:8,13 68:20 69:16
 70:4,8 72:7,16 73:19
 75:7,21 76:10 77:14,20
 85:3 89:6,15 90:15,21
 91:11 93:17 97:22
 98:12
old 8:9,13 29:4
older 22:25 73:5
olds 43:3,4
once 5:4 11:1 37:14 50:21
 71:8 73:22 93:7 94:11
ones 16:11 22:6
online 5:22 18:6 40:25
onset 29:16 42:20
onward 55:9
opinion 27:2 44:7 63:4
 63:11,13,20 64:16,19
 64:25 77:5 82:12,20,25
 83:1,21,24 84:14 85:8
 96:9 97:1
opinions 55:6 64:13 76:7
 76:11,21
optimal 37:17
optimally 33:21
option 93:1
options 91:23 92:2,21
 93:11
oral 37:20 46:3,5
order 13:24 14:11,14
 15:6,6,10 52:4 64:13
 91:5
ordinarily 15:8 21:16
 43:22 44:9 45:20 51:11
 52:20 55:24 57:5 58:15
 60:13,23 61:3 71:8

77:13 91:10
ordinary 28:10 66:10
Oregon 9:1,3
original 42:21 54:14
 98:25
originally 47:16 73:23
orthopedic 64:19
Osos 2:3
outcome 83:23
overall 24:10
overdose 84:25
over-the-counter 90:3,4
owe 98:11

P

P 2:18
package 8:2
page 3:3,9 7:22 49:24
pains 47:14 58:23
Palm 2:11
palpitations 27:9 47:10
 47:13
panel 42:24
panels 14:19 77:11
paper 5:22 21:20 41:21
 41:23
Pardon 93:5
paroxysmal 47:3
part 20:6 23:24 33:19
 34:22 41:12 51:23,25
 76:8 77:19 94:5
particular 12:1,2 17:23
 18:21 19:21 29:22
 57:17 64:14,22 74:23
 74:25 75:25 94:3
particularly 38:7
partners 13:8
parts 69:22 70:3
Paso 8:18,19 10:3 69:25
passed 9:11
pathologist 66:12,15
 83:11
pathologist's 68:21
patient 5:4,11 14:7 15:5
 19:21 21:10,11 22:3
 23:5,18 27:16 28:8
 30:25 32:4 34:9 39:5
 42:5,8,23 52:6 60:12,19
 62:6 93:13
patients 6:15 13:11,13

21:13 23:10 24:6,17
 27:6 28:13 29:21 30:5
 31:9 34:4 35:3,7,14
 37:8 40:16 41:3 48:1
 53:2,5 61:15 88:3,8
patient's 7:10
pattern 37:15
pause 98:16
pay 30:18
PDR 20:10 22:19 65:20
peak 38:5
pectoris 45:6
penalty 99:14
Pennsylvania 26:21
people 29:2,14,25 30:7
 32:16,20 34:12 39:12
 43:13,14 44:13,18
 45:20 47:9 52:19 56:1
 58:11 60:20 61:20 63:7
 63:8 69:24 70:16 72:18
 73:12 74:15,24 81:12
 83:9 90:19 94:7
peoples 44:15
people's 48:10
percent 34:25 48:2 64:5
 64:11 73:11 84:16,17
percentage 24:16 44:15
perform 47:16
period 56:15 60:9 78:6
 91:14 95:25 99:12
periodical 19:1
periods 58:19
perjury 99:15
permanent 46:25
persistent 47:1 72:7
person 10:18,22 11:2
 32:13 37:3 57:9 60:21
personal 96:18
personally 22:1 32:12
pharmaceutical 20:13,19
PHARMACEUTICALS
 2:20,21
pharmacists 21:17
Pharmacokinetics 16:21
Pharmacology 16:19
pharmacy 21:20
phase 47:4
phenomena 34:20
phone 10:21,22 11:3,6,16
physical 14:23

physically 47:16 75:2
 physician 14:22 93:9
 physicians 19:20 34:20
 pick 97:5
 picked 83 13
 pill 29:10,17 84:22
 pills 29:12 40:21 85:6
 pitfalls 83 14
 place 27:25 37:6 53 13
 55:18 101:14
 plain 4 15,17
 Plaintiffs 1:11 2:10
 plan 14:2 91 17,18
 plans 74:1
 plaquing 45:3
 plasma 38:5
 play 38:8
 player 39:22
 please 4:8 49:7
 plus 88:11
 point 25:23 42:9 45:5
 56:25 62:7 71:25
 Political 16:10
 polypharmacy 23 14
 poor 15 13
 popped 40:20,23
 population 23:5 43:25
 65:3
 pose 46:6
 position 17:20
 positions 17:19
 possibilities 71:17 96:25
 possibility 74:6
 possible 7:20 14:4 56:24
 61:18
 possibly 57:15 75:17
 post 91:11
 postmortem 6:18,21 7:16
 18:22 26:20 49 10 50:5
 50:12 52:23 65 11,14
 65:23 66:1,5,8,16,20
 67:9 68:25 77:10,14
 78 11 82 16 83:20
 84:10 85:22 86:3,8
 96:12
 postulating 15:5
 potassium 38:8,11,17
 78:7,12,16
 potassiums 77 19 78:4
 potency 79:11

potential 24:2 39:7
 potentially 78:13 83 15
 pounds 72:10
 practice 12:10,13 19:16
 23:10 24:10 25:3,4
 40:16 42:14 52:19 76:1
 practicing 9:15 31 2,5
 practitioner 75:13
 precipitate 78:13
 precipitated 78:16 84:5
 predated 42:11
 predeath 84:11
 predictable 87:20
 predicting 82:18 84:11
 predictor 52:6
 prescribe 20:21 21 1,8
 24:5,11,13 34:21 47:25
 prescribed 25 16 26 14
 52:20 57:2
 prescribing 24:19
 prescription 20:23 25:8
 47:22 90:2
 present 27:20
 presented 51 7 86:17
 97:1
 presenting 31 16 73:8
 pressure 44:14,15,18,22
 presumably 73:4
 presumed 79:23
 presumptions 80:15
 pretty 21 17 39:11 46:25
 55:10 61:5 73:22 75:19
 92:17 94:9
 prevent 28:5 57:16
 prevention 27:24
 previous 6:1 41:21,23
 86:7
 previously 72:23
 pre-digoxin 35:2
 print 7:22
 prior 9:24 41:24 82:18
 91:6 101:9
 privy 80:13
 probability 27:3 63:4,11
 63:13,21 65 1 76 11
 82:21 83:4
 probable 64:6
 probably 5:6 9:20 19:2
 19:25 22:25 31 15,18
 38:16 43 15 66:6 91:9

problem 43:22 73:5
 problems 13:19,23 34:10
 42:24 86:24
 procedure 69:21 70:13
 70:16,18,23 71:5,17
 72:1 75:10,11 90:23
 91 3,6,6,11 92:9,23
 94:16,18
 procedures 14:13 92:11
 proceeding 101:10
 proceedings 59:5 98:16
 process 4:14 61:12 74:17
 78:7 99:17
 processes 5:12
 produce 61 12
 produced 15:13,15
 product 1:5 8:3,5 28:22
 46:5 65:14 73 15
 production 61 12
 products 21 6 24:17,20
 25:17 26:18 41:6 46:4,6
 56:23
 progress 75:5
 progressed 46:23
 progression 45:5 74:8
 Promise 14:1
 promoted 67 1
 promotion 67:3,4,5
 properties 48:7
 publications 40:11
 published 9:21 41:5
 81:19
 pulmonary 68:22
 pulse 28:25
 purified 34:7
 purpose 25:8 47:21
 purposes 90 18
 put 55:8 58 15 68 1 69:4
 77:8 82:3 84:3 93:8
 99:9
 p.m 1:20,20 2:7 99:25

Q

quality 15 13,15
 quantify 88:10
 quarter 80:7,11,19 81:21
 question 4:21 5:11 6:2
 11 19 14:16 20:22 24:8
 31 1 32:9,11 50:22 52 1
 62:10 64:3 65 16 67:24

68 17 69:24 81 14
 96:24
 questionable 5:5 40:24
 questioning 5:13 76:24
 questions 4:15 13 15
 42:22 64:19 76:25 77:5
 77:7 88:16,24 89:10
 94:24 96 7 98:5,10
 99 16
 quick 98:19
 quickly 20:3
 quinidine 26 15
 quinine 26:15,18,25
 87:22
 quite 9 11 56:3,3 63 16
 quote 51 14 52:1

R

racing 34:16 58:12 75:1
 radiofrequency 70:1,10
 71:20 75:5 93:23
 Ralph 1 9
 ran 66:22
 range 29:22 30:20 38:12
 52:3
 ranges 28 12 30:10,13
 32:21
 ranks 22:11,13
 rapid 28:2,19 29:15,16
 29 16 48:12
 rapidly 48:11 61 14
 rare 46:22
 rarely 65:24
 rate 25:9,11,12 28:13,23
 29:15 30:3 36:4 39:2
 43 15 47:19,23,25 48:4
 48 12 99:24
 rates 28:15 30:1
 ratio 50:6
 rationale 55:22
 reach 13:24 99:20
 reaction 5:5,13 27:5
 reactions 27:10 28:22
 read 17:25 59:6 67:20
 76:20 97:18,19
 reading 7:23 65:18
 real 59:16
 realizing 83:20
 really 8:12 24:8 29:7
 48 14 52:21 61 9 74:22

75:2 95:11
reason 4:22 50:9 61:21
 62:18 72:14 82:3 87:13
reasonable 15:6,20 27:2
 63:11,12,21 64:25
 76:11 82:20
reasonably 14:4
recall 5:10 7:8,11 8:1
 11:4 18:13 20:20 30:14
 41:2 53:20,23 54:1
 58:14,14 62:15 66:18
 71:6,15 73:11 92:8
 94:17 95:19
receive 49:17,19 99:6
received 5:23 49:21
 81:18 85:7
Recess 85:20
recollection 62:1
recommend 70:9
record 23:16 41:18,25
 50:22 56:8 59:4,6 60:7
 60:24 76:20 88:25
 89:22 92:4
records 26:13 41:13,20
 42:15 54:3 57:1 62:2
 65:8 72:5 82:10
recurrent 46:21,23
redistributed 88:11
redistribution 6:18,21
 18:23 50:5 65:11,14
 78:11 83:20 85:23
reduce 25:9 35:22 36:7
reduced 70:19 101:15
refer 69:12 93:7
reference 89:22 90:6
referenced 91:18
reflect 67:9 77:24
regard 91:22 93:23 95:12
 95:23
regarded 22:14
regarding 18:22 21:13,21
 26:22 49:10 54:3 55:9
regards 89:10
regimen 55:23 94:5 95:10
regular 90:3
regularly 17:22 89:24
 90:10
related 35:1 45:23 72:8
relates 1:7 48:6 68:25
relative 32:20
relatively 4:15 28:2 34:18
 43:10,11 48:12 55:25
 60:22
reliability 20:6 68:25
 82:15
reliable 13:24,24 14:3
 15:10,20 22:14 52:5
 64:16 66:20 69:6
reliance 70:19
rely 15:1 21:20
relying 20:8
remained 60:8
remember 5:3,7,14 6:8
 6:10,12,14 9:23 11:17
 18:5 25:18 42:14 53:24
 54:6 56:17,20 58:6 73:1
 92:6
removal 61:12
removed 61:13
renal 23:2,7,18 24:2
 35:10,15,22 36:5,21
 37:5 39:3,7,21 41:7
 44:20 87:16 95:7
report 3:11 20:15,18,19
 45:22 49:9 52:13 54:9
 54:15,22 68:1,21 79:4
 86:11 88:6 95:13
reported 1:22 30:22 50:5
 50:18 51:15
reporter 2:5 98:4 99:4,10
 101:7,24
reporters 2:3 4:18
REPORTER'S 101:4
reports 54:23 55:6 81:21
represent 88:25 89:4
represents 89:7
request 6:4 54:4
required 19:6 91:4
requirements 12:17 19:4
rereading 97:23
research 16:12 18:21
 40:11 65:10,17 85:22
 85:25 97:10
residency 8:22,25
resident 5:4
resources 18:6
response 25:9 28:2,20
 68:2
restore 69:23
restored 57:11
result 26:4 40:17 44:24
 60:25 80:3,25 81:3
results 26:21 29:17,20
 79:14,24
retained 79:19
retarding 48:19
retire 42:12
review 5:21 17:22
reviewed 7:24
reviewing 54:5
RFA 70:25
rhythm 27:21 34:13 47:9
 51:19 57:11,12 69:23
 71:12,13 78:23
rhythms 31:17 38:22
 43:6
right 4:24 5:15 14:24
 15:16 16:1 17:12 18:6
 19:4 22:16 29:10,11
 33:13 36:18,24 38:17
 40:15 41:9,11 56:13
 62:13 64:18 65:25
 75:18 77:25 78:24 80:5
 80:6 81:6 82:9 84:8
 85:13 88:15 90:9 91:20
 92:3 97:6,20
rise 88:18
rises 84:16
risk 23:19 24:3 28:11
 39:8 43:8,20,24 46:7,19
 53:2,13 73:17
risks 20:24 21:2,10 28:8
Robles 8:18,19 10:3
 69:25
Roger 42:7
role 38:8
room 31:17 34:15
round 92:9
routinely 22:2
run 60:6,23 65:4 77:19
 87:10
rural 8:19

S

S 3:8
safely 61:16,21
safety 74:16,17
Sakisha 89:20
sample 26:20 69:1 77:15
 84:21 88:12
sampling 68:25
San 1:19 2:3,12,23 5:16
 8:21 54:20 69:25,25
 100:2 101:2,20
Santa 53:21,25 54:3
 79:18
saw 41:17 46:16 54:5
 70:14 79:23 89:17
saying 20:3 41:1 48:14
 50:15 64:4 78:11 93:14
says 26:2 41:6 50:3,4
 58:4,9,20 59:18 91:21
scan 18:11
scanning 8:10
school 8:20 10:3 13:17
 34:23
science 84:15
scientific 4:16 13:16,23
 15:25 63:22 65:13
sclerotic 44:25
season 72:1
second 5:8 28:5 49:24
secondary 25:13 27:25
 34:10 47:20
section 26:3 27:5 57:23
 58:8
see 8:12 10:9 13:11,13
 29:17 30:12 34:8,9
 41:10 49:22 50:1,7
 52:22 58:1,24 60:2,25
 62:2 66:13 75:16 81:1
 85:19 89:19
seeing 34:12
seen 26:20 27:13,13 30:9
 30:13 33:17 49:15
 54:14,22 61:23 67:16
 69:8 82:2
self-addressed 98:21
sell 73:15
send 98:3,20,21,25 99:3
 99:10
sense 64:9
sent 6:6 7:18
sentence 50:4
sentiment 70:15
separate 25:20 98:1,2
sequence 55:1 57:20
series 77:7 94:24
serum 26:9 29:22 31:21
 33:3,6,15,21 37:7,18

61:23 65:6 67:17 87:1
 87:10,22
service 17:15
set 37:14 71:6 92:24
 101:14
setting 63:14
seven 37:20 42:3
seventies 34:23
SGPT 63:1
shakes 4:19
sheet 98:1,2,3
shock 71:12
shoe 44:14
SHOOK 2:22
short 7:9 25:11 98:16
shorthand 2:2,5 101:6,15
 101:18,24
shortly 81:19
shortness 28:25 74:20
shot 58:17
showed 49:21
shown 6:3
sick 34:16
side 15:20 52:7
sign 39:7 53:18 73:5
 97:18 99:14,19
signals 48:8
significance 42:19 66:16
significant 37:5 40:10
 75:8
signs 31:25 32:2 33:4
 42:24 62:8,21 67:21
 79:5
simple-minded 85:14
single 60:25
sinus 57:11 71:13
sit 96:9,11 97:5,11
site 18:22
situation 11:14 85:15
situations 51:15,16 53:8
six 72:4 79:10
size 44:14,14,14 94:23
skipped 83:16 85:4
slightly 39:23 43:15
slip 54:6
slow 28:14,14,18,24 30:1
 30:8 34:17 74:23
slower 28:25 30:3 38:22
 48:11
slowing 38:21
small 43:10,11,18 44:1
smarter 75:10
societies 16:3
Society 16:5
solid 70:6
somebody 10:9 12:2
 31:21 33:2,6,11 73:4
someplace 44:3
somewhat 32:24
sorry 6:9,23 10:19 17:17
 20:21 24:8 26:11 31:1
 46:12 50:15,19 57:24
 59:25 63:16 65:24 72:2
 76:14 88:2 96:13
sort 13:18 27:15 29:6,7
 70:6
sorts 57:13 66:13 97:10
sound 12:2
Sounded 68:6
Sounds 68:9,14
Source 18:10,12,15
sources 19:25
SOUTHERN 1:2
spastic 51:19
special 16:16,23,25
specialists 19:22
specialty 64:20
specific 89:11
specifically 12:24 22:18
specifics 39:20
specimen 6:17 49:10
 52:23 69:5,6 77:12
 87:14
speculate 63:19 80:24
 81:7 83:17 85:15 92:12
speculation 81:23
speculative 82:1
speeches 40:10
spend 13:5 19:13 85:18
split 55:11 56:1
spoke 28:4
spoken 7:2
sporadically 10:8
spring 9:25
spurs 98:13
ss 100:1 101:1
stabilized 37:15
stable 47:9 60:22
staff 12:6 40:1 41:11
stamped 98:22
stand 85:19
standard 87:20
standards 39:4
stands 50:22
standstill 38:22
Stanford 69:13,16 75:24
start 68:10,13 94:11
started 27:16 42:5 55:15
 55:17
starting 29:12
state 2:5 37:25 70:3
 100:1 101:1,7
stated 34:24
statement 49:25
statements 40:25
states 1:1 12:14 23:11
Statistically 44:17
stays 99:13
steady 37:25
stomach 38:1
stop 45:25 58:13 69:19
 77:3
stopped 87:9
story 51:24
street 2:3,11 94:18
strength 75:25
stress 45:23
strike 80:17
string 64:18
strokes 43:16
structural 53:12 94:15,21
structure 43:17 94:20
structures 94:9
studies 14:10 65:13 97:10
subjects 64:14
subscribe 17:22
subsequent 70:14
subspecialty 9:2 12:25
 64:15
substance 12:8
substantial 86:5
subtle 74:21
success 71:10 73:10,12
 73:16 74:13
successful 91:4 92:9
sudden 43:9,20 47:8 68:7
 68:15
suddenly 61:16
sued 15:18
suffered 40:17
sufficiency 39:3
suit 11:8,13
Suite 2:17
summary 6:23 7:20
summer 69:12 71:4
Sunday 10:21,23
supply 61:11
suppose 23:15
supposed 56:13
supposedly 56:3
sure 20:7 25:19,24 30:19
 31:19 35:13 57:6 64:10
 64:23 68:24 69:15
 71:16 72:3 75:12 76:5
 87:18 97:19,22
surprise 95:17
surprised 98:12
surrounding 96:17
suspect 87:9 92:12
suspecting 14:7
sweaty 47:11
sworn 4:2 101:10
symptom 62:20
symptomatic 47:5 74:19
symptoms 28:6 31:25
 32:2,18 33:4 34:3,11
 47:7 59:15 62:8 67:22
 79:5
syndrome 31:25 32:1
system 50:1

T

T 3:8
tab 58:1
tablet 69:9
tablets 41:2 79:11
take 10:24 14:23 19:6
 29:10,15,17 43:13 49:3
 53:16 58:10,12 60:13
 76:25 83:9 85:17 90:20
 90:20 91:1,17
taken 2:2 4:10 5:1 12:21
 36:11 38:1 59:18 61:16
 61:20 67:17 84:24
 85:18 95:14 101:13,14
 101:19
takes 29:12,20
talk 12:5 41:9 52:14
 66:15 83:11,12 97:21
 97:21 99:18,19

talked 78:12
talking 11:10 12:7 31:24
 52:14 71:21 84:15 92:6
tampering 94:12
target 29:22
taught 13:18
teach 13:23
teaching 9:18 17:19,20
telephoned 11:8
tell 4:8 7:5 10:2 16:15
 28:10,11,17,21 40:9
 42:10 51:24 63:8 78:10
 79:14 81:14 95:14
 99:11 101:11
telling 21:18 51:23
Templeton 7:7 9:16
temporarily 57:5
ten 13:10 22:25 31:18
 33:18 64:4 74:12 95:25
tend 37:12 65:4
tendency 28:14
term 32:20 85:12 91:15
terminology 70:11
terms 28:23 31:13,16
terrible 58:21
tested 79:11
testified 4:3
testify 5:19
testimony 7:5 10:24
Texas 42:14
textbooks 22:15
texts 22:4,9
Thank 91:16 93:17 97:14
 98:17
therapeutic 29:13 50:25
 51:4 52:2,7 86:9,12
 88:2,3
therapies 48:21 51:14
therapy 28:9 48:15 52:2
 52:7
thereof 7:21
they'd 14:8
thickening 94:22
thing 29:6,7 30:20 38:24
 67:25 77:10 92:14
 93:14
things 12:7 13:17 14:18
 14:19 20:2 28:18 30:21
 34:4,8 35:21 36:3,7
 37:3 40:23 44:21 45:20
 47:12 52:8 64:12 67:11
 68:22 75:20 78:8 83:25
 84:3,13,17 97:11,23
think 7:1 10:22 13:5,18
 17:11 19:19 20:2 21:18
 31:11 34:22 36:23
 39:10 40:19 43:12 45:4
 59:3,14 64:12,14 66:4
 68:5 72:24 75:8 77:2
 78:2 79:3 81:22,25 82:7
 83:7 85:11 87:25 89:16
 91:10 95:2 96:19 97:12
 97:17 98:13
thinking 14:15
third 34:24 58:3 92:14
thought 44:20 50:20
 51:21 52:1 57:14 59:15
thoughts 92:1 98:6
threatening 38:20
three 50:13,16 51:1 91:17
 98:14
Thursday 54:19
thyroid 42:23
time 5:12 8:2 10:7 11:2,5
 11:22 13:5 15:1,2 17:17
 19:13,19 22:9 24:23
 27:19 31:8,8 36:13
 37:17 38:4 40:21 43:7
 45:12 57:15 58:19
 59:16 60:9 64:6 67:10
 69:1 70:6 73:20 74:16
 78:6 80:25 82:3 83:22
 84:6,21,22,23,24 86:22
 89:13 91:22 92:14,24
 93:8,24 94:2,3,8,14
 99:12 101:14
times 4:12 10:10,17 11:2
 19:2 23:13 31:11 34:8
 37:16 47:11 50:13,16
 51:1 56:8,9 59:14 63:10
 65:22 66:4 72:24 74:23
 86:20 87:4 94:9 97:21
 98:14
timing 54:13 77:17
tingling 58:21
tiredness 29:1 74:20
tissues 88:12
tobacco 45:25 46:4,5,6
today 5:16,19 10:18 12:6
 25:23 54:5 57:1 82:9
 93:25 96:10,11 97:5,11
today's 7:25
told 29:2 84:9 89:16
tolerance 47:15
tolerated 55:19
tonic 26:17
top 19:3 80:3
topic 6:14 7:13 88:19
topics 85:25
Totowa 1:13 2:15
touched 10:8
town 10:19
toxic 32:13,23,24 51:9
 52:3,6 61:17,19
toxicity 7:11 11:19 18:16
 18:18 24:3 29:2 31:9,13
 31:17,23 32:1,5 33:4,20
 34:18 35:1,4,8 36:19
 38:9,12 39:9 52:11,21
 60:3,14 62:4,8 67:22
 68:5 79:5 86:15 96:1,4
toxicologist 82:15
toxicology 16:23 17:6
 22:17
trace 26:24
training 16:16,23,25 17:2
 17:3 33:24 95:23
transcript 97:18,22 98:2
 98:20 99:13 101:18
transcription 101:16
transition 32:23
transported 36:11 38:2
treat 69:19
treated 95:1,15
treatment 14:2 15:7
 69:17 75:3 91:23 92:2
 92:21 93:1,11 94:5
tremendous 19:15
tremendously 67:12 78:4
tried 55:18 69:18 71:14
 71:16
true 15:22 23:6,9 36:1,9
 38:14 95:15 100:7
 101:18
truth 101:11,11,12
try 29:24 30:21 37:19
 73:14
trying 28:5 30:5 57:5
 85:15
TUCKER 2:16
tuning 75:3
turn 83:22
Twelve 17:11
Twenty-five 19:9
twice 4:13 11:4 55:23
 56:5 98:13
Twin 56:18
twisting 83:5
two 5:11 10:15,23 19:7
 40:19 48:3,21 49:20
 56:12 58:16,16 60:13
 69:5 86:20 91:5 99:21
two-shot 60:10,11
two-thirds 92:8
type 10:16 22:8 30:20
 34:10
types 34:3 45:20
typically 23:20 28:7,21
 30:12 37:7 53:5 70:25

U

UDL 2:21
Uh-huh 58:5 90:24
ultimately 14:2 42:1
 71:19
ultrasound 22:7 42:23
um 6:15 9:13 10:15 13:3
 44:13 48:6 51:11 58:10
 71:2 83:2 86:7
umph 48:15,16
unaware 11:13 69:11
 79:22 80:24 86:13
unbeknownst 67:17
unchanged 73:22
unclear 91:21
uncomfortable 28:3 49:3
Uncommon 43:3
undergo 50:5
undergoes 36:13
underlying 23:18 42:24
understand 4:18,21
 63:17,22
understanding 19:11
 34:2 35:3 51:3 63:12
 67:8 70:8
unexpected 35:15
unexpectedly 66:11
unit 75:24
UNITED 1:1
University 8:21,24,25 9:3

75:25
unquote 51:14 52:1
unusual 30:20 43:2 44:4
 48:2 61:6 80:17 81:22
 81:25 82:5
upper 39:14
uric 62:14,17,20,23
use 18:7 26:3 28:12 30:2
 33:25 37:14 48:16
 51:18
useful 86:14
uses 30:15
usual 41:8 68:6
usually 22:2 29:9 37:13
 42:22 56:24 58:10
 62:15 72:17 73:8 75:19
 87:3 99:3

V

v 1:12
vaguely 58:7
valuable 76:1
values 51:20 86:13 88:6
valves 94:23
variable 43:14
variance 65:3
variation 32:14 78:10
varied 91:13
various 23:11
vary 67:11,12 78:2,4,6
vascular 44:19
vaso 51:19
ventricles 48:9
ventricular 25:9,12 28:2
 28:20 48:7,13
verbal 22:2
versa 59:15
verse 30:24
version 5:18
versus 5:13
vice 59:15
VIRGINIA 1:2
vision 29:6
visit 72:6 76:2
visits 45:11 70:14
visual 32:19 34:3,11
Vitae 3:10
volume 36:15 61:9
vomiting 32:19
Von 1:17 2:1 3:4 4:1,9

49:8 88:24 97:17 100:6
 100:14
Vorpahl 7:15

W

walk 94:17
Wall 22:8,11
want 10:24 15:9,19 20:7
 21:15 33:21 35:19
 48:24,25 49:3 52:5
 58:12 63:19 72:2,20
 76:16 77:4,13 81:9,18
 92:15 93:4,6 94:15,24
 96:8,8 98:9,13,20 99:8
wanted 92:18,23
wanting 71:16
warning 26:3
wasn't 56:9 59:15 65:16
 87:14 93:24 94:2 95:11
wasting 36:13
water 26:17
wavelength 31:20
way 13:19 30:7 35:21
 44:12 48:14 64:4 67:25
 69:4 77:8 78:15
ways 32:3 70:7 72:21
 74:10 91:5
web 18:21
Wednesday 54:21
week 10:19 19:2 54:21
 55:6 94:1,1
weekend 49:20
weeks 5:24 54:8 91:14
weighing 92:13
weighs 72:10
weight 44:12 45:9,18,21
welcome 25:23 81:14
well-informed 92:17
well-known 34:20
went 13:16 52:16 84:24
 86:11
WEST 1:2 2:16
we'll 57:13 85:18
we're 31:19 35:13 37:14
 40:20 93:7 98:19 99:18
 99:18
we've 10:8 13:7 49:2
 52:21 83:25 97:3
widely 22:13
wife 71:21

window 38:4
Winkle 69:13,16,20 70:5
 73:8,14 74:5,11,14
 90:23 91:9 92:22 93:7
 94:7
Winkle's 42:7 70:9,15
 75:8 92:7
wish 78:25
withdraw 17:18 19:11
 20:22 31:1
witness 3:3 10:12 32:12
 35:18 36:16 37:11 49:4
 50:24 51:11 59:9 62:11
 63:16 67:25 68:18
 70:22 76:22 79:22
 80:13 82:7 84:13 88:17
 89:6 96:3,25 97:23
 101:9

WITNESS'S 100:4
women 39:13
wondering 57:7
word 23:15 48:16 55:3
 61:19 96:7
words 54:21 82:22 97:20
work 13:9 45:23 97:9
worked 94:23
working 30:20
works 75:13
world 82:2
worried 86:18
worry 28:14
worse 73:20
worsening 74:9
wouldn't 48:16 56:5 57:6
 61:9 67:12 74:10 78:18
written 10:14 82:10
wrong 84:4

X

X 3:1,8

Y

yeah 13:21 18:2 19:5,10
 22:6,9 23:15 25:6,12
 26:7 32:12 38:22 50:24
 61:11 62:21 84:13
 90:13 95:18 96:3 97:24
 99:5
year 9:4 10:5,10 19:8,9
 24:25 37:16 40:19

42:10,14 43:3,4 80:7,11
 80:19 81:21 90:6
years 5:6 9:22 10:9 12:21
 13:7,10 17:12 18:19
 19:7 22:25 30:23 33:25
 37:2 42:3 44:19,19
 47:12 52:20 53:7 55:16
 61:2 69:15 73:4 74:12
 74:14 95:2,2,25
yep 45:10 72:2,2,2,11
young 39:11,13 65:3 84:3
younger 60:21 72:21

Z

zone 74:16

#

#7281 1:22

1

1 3:10 40:4,5
1.5 30:5
10 10:9 24:18
10,000 83:9,21
100 73:11
100,000 43:13,14
1020 2:11
11-27-06 90:7
11-29-07 89:12 91:17
 93:3
1150 2:17
12 95:2
13 17:11 95:2
130 44:17
1302 2:3
14 95:2
14th 101:20
140 44:16
15 65:7
16 57:18,19
18 73:4
180 56:11
1986 9:17 17:14
1992 41:17
1994 55:9 56:18
1998 41:19

2

2 3:11 7:14 49:7,9,12,25
 66:3 80:3 84:16 87:8
 88:7 91:25

2.0 29:24 30:3,12,22 31:14,22 32:14	50 31:2 50:25 55:10 59:19 64:5,11
2.25 55:11	541-0300 2:13
2.6 50:6	544-1900 2:24
2:03 1:20 2:7	58 8:14
2:09-CV-0671 1:8	59 8:14
20 5:6 10:9 24:18 34:25 48:2 84:17	592-5000 2:18
200 50:25	<hr/> 6 <hr/>
2000 57:18,19	630 50:12,15,15 51:1,8 51:24 86:4
2001 64:24 72:5 74:1,3	<hr/> 7 <hr/>
2006 90:12	70 77:15 88:11
2007 25:25 46:9,15 56:10 64:24 65:7 69:12 71:4 71:25 72:6 74:5 75:16	72 69:6
2008 3:11 9:25 11:10 49:10 80:5 81:20	<hr/> 8 <hr/>
2009 1:18 2:6 11:10,11 100:10 101:21	8 30:12 88:7
21 43:3	80 44:17
21st 11:7	805 2:13
216 2:18	88 3:5
22 42:17 43:4	<hr/> 9 <hr/>
225 72:10	90 44:17
24 55:25 56:3,4,14 67:18	90s 31:6
24th 3:11 49:9 80:4	925 2:17
24-hour 56:15	93 3:6
25 19:8 55:23 58:1 73:24 86:19 99:22	93401 2:12
2555 2:23	94104-2828 2:23
29th 72:6 75:16	
<hr/> 3 <hr/>	
3.6 82:16 84:10 96:15	
30 5:6	
30-day 99:12	
300 56:11	
325 90:4	
<hr/> 4 <hr/>	
4 3:4	
4:26 1:20 99:25	
40 3:10 72:9	
415 2:24	
44115-1414 2:17	
49 3:11	
<hr/> 5 <hr/>	
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